S. HRG. 100-394, PT. II

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARINGS

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

S. 1516

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AND FOR OTHER PURPOSES (FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT REFORM OF 1987)

APRIL 29, MAY 20, AND JULY 30, 1987

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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Federal Insecticide, Fungicide, and Rodenticide Act Reform of 1987, S. 1516

THURSDAY, JULY 30, 1987

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 10:15 a.m., in room SD-562, Dirksen Senate Office Building, Hon. Patrick J. Leahy (chairman of the committee) presiding.

Present or submitting a statement: Senators Leahy, Melcher, Pryor, Harkin, Fowler, Daschle, Breaux, Lugar, Helms, Cochran, Boschwitz, Bond, Wilson, and Karnes.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The CHAIRMAN. The committee will be in order. Last week Senator Lugar and I introduced a bipartisan bill to reform and improve our Nation's pesticide law, the Federal Insecticide, Fungicide, and Rodenticide Act. We are going to hear testimony about it today. I am pleased to be here this morning to listen to testimony on this legislation. Because we have over 20 witnesses today, I will keep my remarks brief and ask that other Senators do the same. To speed things up, I will put my prepared statement in the record, except to say I want to thank my good friend, Dick Lugar, for his commitment while working together on this issue.

We joined forces on the 1978 amendments back when we were both young, and we aged rapidly during that time. The aging process was more apparent with me than with Dick, but we got it through, and I think we can do that again.

[The prepared statement of Chairman Leahy follows:]

U.S. SENATOR PATRICK LEAHY

VERMONT

OPENING STATEMENT
HEARING ON THE FIFRA REFORM OF 1987
JULY 30, 1987

Last week Senator Lugar and I introduced a bipartisan bill to reform and improve our Nation's pesticide law, the Federal Insecticide, Fungicide, and Rodenticide Act. I am pleased to be here this morning to listen to testimony on this legislation. Because we have over twenty witnesses today, I will keep my remarks brief and ask that other Senators do the same.

It's been almost a decade since Congress passed any significant amendments to FIFRA, and reform is long overdue. In 1972 and again in 1978, Congress ordered the Environmental Protection Agency to review the health and safety data on some 600 pesticide ingredients. To date, the Agency has thoroughly investigated only two of these products. The rest continue to be marketed while evidence mounts that many of these chemicals leach into ground water, cause cancer, or otherwise adversely affect human health and the environment.

The inadequacies of current law are a well-known part of the problem. The Agency lacks not only the legislative tools they need to get the job done, but also the funds.

The Leahy/Lugar bill addresses both of those problems. It is based on the FIFRA amendments that passed the House of Representatives in the closing days of the 99th Congress, with a few important revisions. That bill reflected an extraordinary agreement reached after years of negotiation by the environmental community, the chemical industry, consumer and labor groups, and the American Farm Bureau Federation.

The Leahy/Lugar bill will correct some of the serious shortcomings of last year's bill. First, we have designed a new reregistration fee schedule that will give EPA the resources to finish reregistration in nine years, instead of sometime in the next century.

Second, we have included last year's Senate-passed language on indemnification. Congress will have to approve a line item advance appropriation before the Agency can pay pesticide producers for stocks of pesticides taken off the market because they pose an imminent health or environmental hazard.

And finally, our bill reflects last year's Senate position on uniform tolerances for pesticide residues on food. I believe that we must preserve the right of States to set more stringent standards if they so choose. Every other Federal environmental statute allows them to do so. Marketing convenience is not a sufficient reason to start chipping away at States' right to protect their citizens.

I expect that other Senators and the interest groups have their own list of improvements to be made in the bill. I am looking at further improvement of my own. It is my hope, though, that this Committee and the Congress can reach a consensus and send a bill to the President this fall. Time has been the enemy. That's why we started early, and that's why we intend to move expeditiously on this bill.

In closing, I want to thank my good friend and ranking member, Senator Lugar, for his commitment to work together again on FIFRA reform. We joined forces on the 1978 amendments, and I will be counting on his leadership and cooperation on this initiative.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator LUGAR. Mr. Chairman, I will ask unanimous consent that my statement be made a part of the record. I have just tried to review, as we did in our opening press conference on the FIFRA bill, the various disagreements that are still there, but likewise, a broad consensus that a large coalition of Americans has brought to the so-called October 16 bill. Much of our efforts are based upon that work, plus or minus a few sections that have been omitted pending committee action, and pending certainly the thoughtful hearing that we anticipate today.

Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Senator Lugar follows:]

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Mr. Chairman, I am pleased that you have called this hearing promptly to review the provisions of S. 1546, the FIFRA reauthorization bill that we recently introduced. I am hopeful that we can move expiditiously to consider this bill shortly after the August recess.

This legislation is virtually identical to broadly supported legislation that passed both bodies of Congress last year, but failed to secure final approval by the Senate on the final day of the session. It represents over two years of negotiations and compromise among competing interests in the pesticide area. This omnibus bill was endorsed last year by the National Agricultural Chemicals Association, a coalition of forty-one environmental and labor groups, and the American Farm Bureau Federation.

Without question the most significant aspect of this legislation is the reregistration of older pesticides. Prior to the creation of the Environmental Protection Agency in the early 1970's, pesticides were regulated by the Department of Agriculture using standards that were far less stringent than today's requirements for registration. Despite two mandates by Congress in 1972 and again in 1978 to review and reregister some 600 active ingredients, the EPA has reregistered less than one percent of these products. These active ingredients continue to be registered and marketed today despite the fact that adequate health and safety data may not be available to support such a registration.

Last year's legislation improved upon previous reregistration mandates because it authorized the EPA to require registrants to pay a one-time user fee of $150,000 for each reregistered active ingredient. Since this time, the EPA has made the case that the reregistration fee remains inadequate to fund the programs within the time periods mandated in this bill.

We have therefore rewritten the reregistration fee section in an attempt to generate more revenues for the EPA on an annual basis. The new legislation generates about $11.3 million in fees compared to last year's bill that generated about $44 million. I would specifically ask that each witness focus upon the impact of this change in his or her testimony.

The legislation resolves other issues that in the past have bitterly divided environmentalists and the pesticide manufacturing industry. The bill establishes a system whereby the public may review health and safety data used to support an EPA pesticide registration in order to ensure that the EPA is following the guidelines established under FIFRA. In addition, the bill enacts time deadlines for administrative review of registered pesticides suspected of causing adverse effects upon public health and the environment.

The bill also directs the EPA to establish a new program to regulate inert ingredients in pesticides. The EPA has identified approximately fifty-five inert ingredients out of 2000 known to cause adverse health and environmental effects.

Finally, the bill contains the so-called patent-term restoration provisions that enable the original registrants to obtain a patent extension for the period of time necessary for the Environmental Protection Agency to review and approve the pesticide registration. Such a provision will encourage the pesticide manufacturers to invest in costly research programs to develop safer and more effective pesticides.

I would also encourage today's industry panel to focus upon the data compensation issue which is of great interest to Senator Melcher and others. Senator Kassebaum will be testifying of her data compensation bill and the hearing record should reflect any concerns or suggestions regarding this legislation.

— — - - -

The CHAIRMAN. I welcome the person who, without a doubt, is one of the most respected Members of the U.S. Senate, Senator Kassebaum, the Senator from Kansas. We are delighted to have you here, and I apologize for being late.

STATEMENT OF HON. NANCY LANDON KASSEBAUM, A U.S. SENATOR FROM KANSAS

Senator KASSEBAUM. Thank you very much, Mr. Chairman and Senator Lugar. I appreciate being here. I know that both of you have spent a great deal of time on this subject. I am certainly no expert. I am slowly learning about FIFRA. I have learned more than I ever thought I would. I am involved in the issue, and it is an extremely important one, with all of the divisions of concerns regarding it, but I largely became involved because of one certain part of it that I believe could be a great help to our farmers.

I think that today, as always, we wish to do what we can to help farmers achieve some breaks where they can on the high cost of production. As you know, Mr. Chairman, Senator Gore and I have introduced S. 746, the Pesticide Price Competition Act, providing for the generic registration of pesticides. Senators Dole and Sasser are now cosponsors of this bill, I am pleased to say.

I note with considerable interest that S. 1516 calls for the adoption of patent term restoration for pesticides. In my opinion, this makes a discussion of data compensation reform especially relevant.

I think it is appropriate that we amend our patent code to recognize the fact that regulatory delay in granting a license to market a pesticide can shorten by several years the effective life of the patent. So I support the provision that you have written into S. 1516 to extend patent protection on pesticides for up to 5 years. This will assure that the originator of new pesticides which are so important to the agricultural community, will receive sufficient patent protection to recover their research and development expenditures.

However, it is precisely this provision of the patent term restoration which I believe commends S. 746 to the attention of the members of this committee. In 1984 when Congress decided to grant patent term restoration to the pharmaceutical industry, it also decided to provide for the generic registration of drugs. That decision was well taken. The granting of extended patent protection has encouraged increased expenditures for research and development. Statistics from the Pharmaceutical Manufacturers Association show that in 1984, the year that patent term restoration and data compensation reform were passed, research and development spending increased by 10.9 percent over the previous year. Similarly, research and development expenditures increased by 13.9 percent in 1985, and by 14 percent in 1986. At the same time, generic registration has meant greatly expanded competitive pricing opportunities for consumers.

Mr. Chairman, I would like to ask that my full statement be a matter of record, but I am going to skip a bit because you do have a long agenda.

The CHAIRMAN. Without objection.

Senator **Kassebaum**. As you know, large amounts of costly and complex data are required to be submitted to the Environmental Protection Agency in order for a pesticide to be registered and marketed. Under current law, a company which is interested in manufacturing a pesticide generically must either duplicate the original research to generate its own data or purchase the right to cite the data compiled by the original manufacturer. The result is either inefficient duplication of research or costly purchase of data. Both options serve as formidable barriers to entry into the generic pesticide market.

As an example, let me cite the only case to this point decided under current data compensation law. In that case, *Stauffer* v. *PPG Industries*, the arbitrators provided for an award to Stauffer which, based on the arbitrators' own estimates, will amount to more than $15 million. The total cost of the data in this case was approximately $3 million. In other words, the generic company was required to pay the originating company more than five times the cost of the data. This seems to me an exorbitant amount to award to a company which has already had the full 17-year patent period to recoup its research and development costs as well as a reasonable profit.

Definitive savings to agricultural producers are difficult to come up with because no detailed analysis is available showing absolute effect of generic pesticide production on competition and prices. Estimates from within the industry place potential savings to farmers in the range of $200 to $500 million annually. In general, from data available, it appears that prices usually decrease by approximately 20 percent when two or more manufacturers offer the same pesticide in the market.

Some will make the argument that allowing generic producers to have a free ride without paying for the data they must submit will kill research and development initiatives in the pesticide industry. I do not believe this is the case. Manufacturers are provided with a 17-year exclusive marketing right over registered pesticides. If patent term restoration is passed, this could be extended by an additional 5 years. In addition, manufacturers are eligible for research and development tax deductions and credits. I believe these provisions offer adequate incentives for innovation. I think that a good, healthy dose of competition will be useful for the industry, while at the same time substantially lowering the costs of pesticides to farmers and expanding their purchasing options.

Given this situation, I think it would be a great disservice to farmers if the Congress were to adopt patent term restoration without changing the present procedure for data compensation. But if we combine both provisions, I sincerely believe that we will have produced real benefits for everyone involved; the basic manufacturers, the generic producers, and more importantly, the farmers all would be winners. So I strongly urge the committee to link patent term restoration to reform of data compensation. I, of course, firmly believe that the most meaningful and rational reform would be the generic registration along the line provided by S. 746. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kassebaum. I appreciate not only the testimony, but your consideration of what has to be probably the least glamorous, but one of the most complex and important issues we are going to have here this year.

[The prepared statement of Senator Kassebaum follows:]

STATEMENT ON FIFRA
BEFORE THE COMMITTEE ON AGRICULTURE
by Senator Nancy Landon Kassebaum
July 30, 1987

Mr. Chairman, I appreciate the opportunity to testify before the committee today on the data compensation provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). I feel that this issue is an important one to our farmers and one which could really give them a break on some of their high input costs.

Mr. Chairman, as you may know, Senator Gore and I have introduced S. 746, the Pesticide Price Competition Act, providing for the generic registration of pesticides. Senator Dole and Senator Sasser are also cosponsors of the bill. I note with considerable interest that S. 1516 calls for the adoption of patent term restoration for pesticides. In my opinion, this makes a discussion of data compensation reform especially relevant.

I think it is appropriate that we amend our patent code to recognize the fact that regulatory delay in granting a license to market a pesticide can shorten by several years the effective life of a patent. So I support the provision you have written into S. 1516 to extend patent protection on pesticides for up to five years. This will assure that the originator of new pesticides, which are so important to the agricultural community, will receive sufficient patent protection to recover their research and development expenditures.

However, it is precisely this provision of patent term restoration which I believe commends S. 746 to the attention of the members of this committee. In 1984 when Congress decided to grant patent term restoration to the pharmaceutical industry, it also decided to provide for the generic registration of drugs. That decision was well taken. The granting of extended patent protection has encouraged increased expenditures for research and development. Statistics from the Pharmaceutical Manufacturers Association show that in 1984, the year that patent term restoration and data compensation reform were passed, research and development spending increased by 10.9 percent over the previous year. Similarly, research and development expenditures increased by 13.9 percent in 1985 and by 14.0 percent in 1986. At the same time, generic registration has meant greatly expanded competitive pricing opportunities for consumers.

The present system of data compensation for pesticides--which S. 746 would replace--is having a chilling effect on generic pesticide production. The mechanism put in place by the 1978 amendments to FIFRA serve to discourage follow-on, generic production. This clearly works to the detriment of our farmers who are increasingly being denied the benefit of competitively priced generic pesticides.

As you know, large amounts of costly and complex data are required to be submitted to the Environmental Protection Agency in order for a pesticide to be registered and marketed. Under current law, a company which is interested in manufacturing a pesticide generically must either duplicate the original research to generate its own data or purchase the right to cite the data compiled by the original manufacturer. The result is either inefficient duplication of research or costly purchase of data. Both options serve as formidable barriers to entry into the generic pesticide market.

As an example, let me cite the only case to this point decided under current data compensation law. In that case, Stauffer vs. PPG Industries, the arbitrators provided for an award to Stauffer which, based on the arbitrators' own estimates, will amount to more than $15 million. The total cost of the data in this case was approximately $3 million. In other words, the generic company was required to pay the originating company more than five times the cost of the data. This seems to me an exorbitant amount to award to a company which has already had the full seventeen-year patent period to recoup its research and development costs as well as a reasonable profit.

Mr. Chairman, this is not a radical or unusual proposal. The same concept of coupling generic registration with patent term restoration has been implemented in the pharmaceutical drug industry and the veterinary drug industry. The results in both of these industries has been increased competition and more options for consumers. Especially when paired with patent term restoration, which could increase the patent period to as long as twenty-two years, allowing information to be in the public domain upon patent expiration seems to be a fair approach to all parties involved.

Definitive savings to agricultural producers are difficult to come up with because no detailed analysis is available showing the absolute effect of generic pesticide production on competition and prices. Estimates from within the industry place potential savings to farmers in the range of $200 million to $500 million annually. In general, from the data available, it appears that prices usually decrease by approximately 20 percent when two or more manufacturers offer the same pesticide in the market.

Farmland Industries, a farmer-owned cooperative which is interested in marketing generic versions of widely used pesticides, conducted a study last year of four major pesticides used in U.S. agriculture. The pesticides examined were Lasso, Dual, Bladex, and Round-up. If the patent on each of these products expired, generic competition entered the market, and the price dropped by 20 percent, the total annual savings on these four products alone would be approximately $208.6 million. The patents of these products are all expired by 1993, so you can see that this projection is of real significance to farmers.

Some will make the argument that allowing generic producers to have a "free ride" without paying for the data they must submit will kill research and development initiatives in the pesticide industry. I do not believe this is the case. Manufacturers are provided with a seventeen-year exclusive marketing right over registered pesticides. If patent term restoration is passed, this could be extended an additional five years. In addition, manufacturers are eligible for research and development tax deductions and credits. I believe these provisions offer adequate incentives for innovation. I think that a good, healthy dose of competition will be useful for the industry, while at the same time substantially lowering the costs of pesticides to farmers and expanding their purchasing options.

Given this situation, I think it would be a great disservice to farmers if the Congress were to adopt patent term restoration without changing the present procedure for data compensation. But if we combine both provisions, I sincerely believe that we will have produced real benefits for everyone involved; the basic manufacturers, the generic producers, and most importantly, the farmers all would be winners. So I strongly urge the committee to link patent term restoration to reform of data compensation. I, of course, firmly believe that the most meaningful and rational reform would be generic registration along the line provided by S. 746.

In summary, Mr. Chairman, I want to stress the potential impact of this legislation on American agriculture. By allowing our farmers to be more competitive in world markets, we can help to ensure the future survival of our farm infrastructure, the most productive and efficient in the world. However, the only way we can do this is to hold down costs of production. We are all concerned about the condition of agriculture in our country and its ability to compete. Helping farmers to reduce their input costs and maintain net farm income through this legislation would be a significant step. Our farmers compete in one of the most brutally competitive marketplaces in the world. It is only fair that pesticide manufacturers be allowed to do the same. By providing this type of competition in the marketplace, we could give our farmers a break without further drain on the U.S. Treasury.

Thank you, Mr. Chairman, for this opportunity to share my views on this important legislation before the committee. I would be glad to respond to any questions you may have.

The CHAIRMAN. I yield to Senator Lugar and welcome Senator Helms and Senator Cochran to the committee.

Senator LUGAR. Mr. Chairman, Senator Kassebaum, clearly one of the most important parts of your prepared statement is the thought that you suggest at the bottom of page 2: "Some will make the argument that allowing generic producers to have a 'free ride' without paying for the data they must submit will kill research and development initiatives." And you say, "I do not believe this is the case," and you have cited increases in research and development in various years.

As I have heard this issue argued, indeed it does often come down to this. Those who are involved in the research and the development of pesticides believe that the odds, often of success, in this business are slim. I do not know how—they could better express how many times they go to the well trying to come up with a pesticide that meets all the tests and requirements and what have you—many times they fail.

But everybody agrees that their success is important in terms of American agriculture and other applications. So on the one hand, they want a return on their money invested in all this over the course of the long period of time. I suppose they will argue that if, in fact, their returns are cut off at a certain point after the patent time runs out, or the time beyond that, that they have been fairly compensated. And as you pointed out, the one case, the *Stauffer* case, came down fairly heavily, as your testimony points out, on behalf of the chemical companies which may have prompted your legislation.

Can you guide us to any other studies or testimonies that are helpful on this crucial point? Because it is one in which the committee will have to come down, I suppose, on one side or the other. Or can you give us a formula for data compensation? It may not be the same one of going to arbitration or as generous as the one we now have, but I can see that this is going to be a point of contention.

Senator KASSEBAUM. As far as research and development, you mean any statistics that would show——

Senator LUGAR. Yes. I suppose we are really dealing with human motivation and why people make decisions to continue. As I say, I think we are going to hear arguments that this field is not going to have the research and attention if, in fact, people are not compensated for their work. Sort of a drying up of breakthroughs and innovations in this area.

Senator KASSEBAUM. Well, it is difficult to get the statistics that one can base a decision on. It just seems to me that some of it, to a certain extent, has to rest on common sense. That after 20 years—if there is the term restoration 5-year extension, that would be 22 years in which there would be a protection.

It seems to me during that period of time there should be the opportunity to recoup, certainly initial investment, and with the tax incentives that there are, this is useful. There are some figures in comparison, as I say, to what happened with pharmaceuticals. Whether you can transpose that to the sort of uniqueness of this area because I suppose one could argue it is not as large a demand for use as there might be with the pharmaceuticals over a period of time.

Senator LUGAR. What happened in pharmaceuticals? Can you guide us in that comparison?

Senator KASSEBAUM. Well, I have some statistics from the Pharmaceutical Manufacturers Association. As a matter of fact, regarding research and development, it actually increased after 1984 when the data compensation requirements were removed. In 1984, they rose by 10.9 percent from 1983. And the next year, they rose 13.9 percent from the 1984 level, and the next year 14 percent. So each year they have risen much above the previous year.

I do not think, at least from those statistics, it would indicate that they were thwarted in any way from that provision.

Senator LUGAR. Thank you.

The CHAIRMAN. Senator Helms, you said you had a statement on FIFRA?

STATEMENT OF HON. JESSE HELMS, A U.S. SENATOR FROM NORTH CAROLINA

Senator HELMS. Mr. Chairman, I thank you very much. I have a meeting downtown at 11 o'clock.

The CHAIRMAN. Then we are safe from votes at 11 o'clock?

Senator HELMS. I do hope so. Probably safe anyhow. But I thank the chair, and we are all friends here. Sometimes we disagree, but we always agree to disagree agreeably, and I am bound to observe that the FIFRA bill that we considered last year was a good bill. It was, in fact, an historic measure that culminated 2 years of often heated negotiations and compromises of many interests, and Senator Lugar can testify to that. That bill was endorsed by the National Chemicals Association, a coalition of 41 environmental and labor groups, and the American Farm Bureau Federation, among others.

Now with all due respect, S. 1516 negates all the negotiations and compromises the members of this committee worked so diligently to accomplish. Three fundamental provisions have been eliminated from last year's package, and the absence of these provisions tilts the delicate balance reached last year resulting in legislation I think you are going to find is totally unacceptable.

We shall see about that, of course. In any case, Mr. Chairman, I have just received a letter from the North Carolina Farm Bureau Federation. Bob Jenkins is president, a good guy, very knowledgeable. And Bob outlines the Farm Bureau's objections to S. 1516, and I ask respectfully that this letter be made a part of the hearing record.

The CHAIRMAN. Without objection.

Senator HELMS. He says, among other things, he has four provisions, and I will not go into all of them, but in provision two, he states; "National uniform tolerances for pesticide and herbicide residues must be established. States should not be permitted to establish pesticide residue tolerances different from those established by the EPA." And I fully agree with that.

Now, over the past 3 years, a handful of States have set up what I consider to be a dangerous precedent by refusing to accept federally established safety levels for chemical residues in foods. These

States have not only disagreed with the Federal Government's safety limits, but have disagreed among themselves over both the range of products covered and the permissible level. This inconsistency led to a situation where farmers could not sell "safe"—and I put safe in quotation marks—as determined by the U.S. EPA, safe grain and other farm products nationwide; food processors could not ship "safe" food products nationwide; food retailers could not sell "safe" food products, and consumer food prices increased and product choices decreased as nationwide distribution was needlessly, in my judgment, disrupted.

Now, as I said, Mr. Chairman, I am not going to throw all the hay down from the loft at this point, but I do appreciate your letting me make these few comments, and for agreeing to put my statement in the record along with Bob Jenkins' letter.

The CHAIRMAN. Thank you very much, Senator Helms.

Senator HELMS. Thank you, Mr. Chairman.

[The prepared statement of Senator Helms and the letter from the North Carolina Farm Bureau Federation follow:]

SENATOR JESSE HELMS
FIFRA HEARING
JULY 30, 1987

MR. CHAIRMAN, THE FIFRA BILL WE CONSIDERED LAST YEAR WAS A GOOD BILL -- AN HISTORIC MEASURE THAT CULMINATED 2 YEARS OF OFTEN HEATED NEGOTIATIONS AND COMPROMISE OF MANY INTERESTS. THAT BILL WAS ENDORSED BY THE NATIONAL CHEMICALS ASSOCIATION, A COALITION OF 41 ENVIRONMENTAL AND LABOR GROUPS, AND THE AMERICAN FARM BUREAU FEDERATION.

S.1516 NEGATES ALL THE NEGOTIATIONS AND COMPROMISES THE MEMBERS OF THIS COMMITTEE WORKED SO DILIGENTLY TO ACCOMPLISH. THREE FUNDAMENTAL PROVISIONS HAVE BEEN STRIPPED FROM LAST YEAR'S PACKAGE. THEIR ABSENCE TILTS THE DELICATE BALANCE REACHED LAST YEAR RESULTING IN LEGISLATION THAT IS TOTALLY UNACCEPTABLE.

MR. CHAIRMAN, I HAVE JUST RECEIVED A LETTER FROM THE NORTH CAROLINA FARM BUREAU OUTLINING THEIR OBJECTIONS TO S.1516. I ASK THAT THIS LETTER BE MADE A PART OF THE HEARING RECORD.

OF GREAT CONCERN TO ME IS THE LACK OF LANGUAGE ON NATIONAL UNIFORM TOLERANCES FOR PESTICIDE AND HERBICIDE RESIDUES.

OVER THE PAST THREE YEARS, A HANDFUL OF STATES HAVE SET A DANGEROUS PRECEDENT BY REFUSING TO ACCEPT FEDERALLY ESTABLISHED SAFETY LEVELS FOR CHEMICAL RESIDUES IN FOODS. THESE STATES HAVE NOT ONLY DISAGREED WITH THE FEDERAL GOVERNMENT'S SAFETY LIMITS, BUT HAVE DISAGREED AMONG THEMSELVES OVER BOTH THE RANGE OF PRODUCTS COVERED AND THE PERMISSIBLE LEVEL. THIS INCONSISTENCY LED TO A SITUATION WHERE:

* FARMERS COULD NOT SELL "SAFE" (AS DETERMINED BY THE U.S. EPA) GRAIN AND OTHER FARM PRODUCTS NATIONWIDE;
* FOOD PROCESSORS COULD NOT SHIP "SAFE" FOOD PRODUCTS NATIONWIDE;
* FOOD RETAILERS COULD NOT SELL "SAFE" FOOD PRODUCTS; AND
* CONSUMER FOOD PRICES INCREASED AND PRODUCT CHOICES DECREASED AS NATIONWIDE DISTRIBUTION WAS NEEDLESSLY DISRUPTED.

THE MOST RECENT EXAMPLE OF THIS PROBLEM OCCURRED IN MAY 1986, WHEN MAINE AND MASSACHUSETTS IGNORED THE FEDERAL STANDARDS FOR PERMISSIBLE LEVELS OF ALAR, A GROWTH HORMONE USED ON FRUIT TREES, AND SET THEIR OWN DIFFERENT STANDARD. GROWERS WERE UNCERTAIN WHETHER TO TREAT THEIR CROP. CONSEQUENTLY THE APPLE HARVEST IN THE NORTHEAST FELL ALMOST

25%, ACCORDING TO THE NEW YORK-NEW ENGLAND APPLE INSTITUTE. THE RESULTS OF THIS SHORTAGE WERE DECREASED PROFITS FOR FARMERS AND IN SOME CASES, A 10% INCREASE IN CONSUMER PRICES.

VIRTUALLY EVERY FOOD PRODUCT FROM APPLES TO ZUCCHINI SQUASH MAY BE THREATENED BY INDIVIDUAL STATE ACTION AS EPA CONTINUES ITS ACCELERATED REVIEW OF THE MORE THAN 300 OTHER "FOOD USE" CHEMICALS. A PARTIAL LISTING OF POTENTIALLY AFFECTED FOODS APPEARS BELOW.

FOODS POTENTIALLY AFFECTED BY DIFFERING STATE ACTION

APPLES
AVACADOS
BANANAS
BLUEBERRIES
BROCCOLI
CARROTS
CHERRIES
CITRUS
COFFEE
CORN
CRANBERRIES
EGGS
LETTUCE
MACADAMIA NUTS
MEAT
PEACHES
PEARS
PEANUTS
PINEAPPLES
PORK
POTATOES
POULTRY
RAISINS
RICE
SOYBEANS
STRAWBERRIES
SUNFLOWER SEEDS
SUGAR BEETS
SUGAR CANE
TOMATOES
WATERMELONS
WHEAT
ZUCCHINI SQUASH

BECAUSE OF THE SERIOUSNESS OF THIS PROBLEM OF INCONSISTENT OR CONFLICTING STANDARDS AND REQUIREMENTS FOR PESTICIDE RESIDUE IN FOOD, HAVING NATIONAL UNIFORMITY LANGUAGE IN THE FIFRA LEGISLATION IS VITALLY IMPORTANT. I THINK IT IS NECESSARY TO EXPLAIN EXACTLY WHAT NATIONAL UNIFORMITY STANDARDS DO AND DO NOT DO.

BASICALLY THEY PROVIDE FOR NATIONAL UNIFORMITY IN THE REGULATION OF PESTICIDE RESIDUES IN OR ON FOOD IN ORDER TO FACILITATE NATIONAL PRODUCTION AND MARKETING OF ALL FOODS WITHOUT JURISDICTIONAL BARRIERS. AT THE SAME TIME NATIONAL UNIFORMITY STANDARDS RECOGNIZE THE NEEDS OF THE STATES TO ESTABLISH TOLERANCES STRICTER THAN THE NATIONAL LEVELS. A STATE COULD PETITION FOR AN EXEMPTION FROM THE NATIONAL PESTICIDE RESIDUE LEVEL IF A DIFFERENT REQUIREMENT IS JUSTIFIED BY, FIRST, COMPELLING LOCAL CONDITIONS; SECOND, WOULD NOT UNDULY BURDEN INTERSTATE COMMERCE; AND, THIRD, WOULD NOT CAUSE ANY FOOD TO BE IN VIOLATION OF FEDERAL LAW.

IN ADDITION, NATIONAL UNIFORMITY STANDARDS ALLOW A STATE TO ESTABLISH STRICTER TOLERANCES IN CASES OF A SUBSTANTIAL RISK OF SERIOUS HARM TO HUMAN HEALTH UNTIL THE EPA ADMINISTRATOR ACTS UPON A STATE'S PETITION FOR A DIFFERING REQUIREMENT. SINCE THIS PROVISION WAS MODIFIED DRASTICALLY DURING THE 85 FARM BILL DEBATE TO ADDRESS CONCERNS RAISED BY THE ENVIRONMENTAL COMMUNITY, IT REPRESENTS A FAIR COMPROMISE AMONG COMPETING INTERESTS. IN ADDITION IT STRIKES A CAREFUL BALANCE BETWEEN FEDERAL AND STATE AUTHORITY TO REGULATE PUBLIC HEALTH AND SAFETY.

MR. CHAIRMAN, I WILL HAVE TO CONCLUDE BY SAYING I WILL NOT SUPPORT S.1516 IN PRESENT FORM. THE SENATE MUST ADDRESS THE ISSUES I'VE DISCUSSED WHILE CONSIDERING FIFRA IF WE TRULY WANT TO HELP THE FARM COMMUNITY.

(The letter from the North Carolina Farm Bureau Federation follows:)

NORTH CAROLINA
FARM BUREAU FEDERATION

TELEPHONE (919) 782-1705 / P. O. BOX 27766 / RALEIGH, NORTH CAROLINA 27611

July 27, 1987

Honorable Jesse Helms
United States Senate
403 Dirksen Office Building
Washington, D.C. 20510

Attn: Mark Fleming

Dear Senator Helms:

Senators Leahy and Lugar have introduced S. 1516, legislation to amend the Federal Insecticide, Fungicide and Rodenticide Act. Though we have not yet seen a copy of the bill, the summary information we have received causes us concern.

The major provisions which Farm Bureau sought in FIFRA legislation during the 99th Congress are not contained in S. 1516. We feel very strongly that such provisions are reasonable, responsible and in the public interest to be included in any amendments to the Act. Those provisions are as follows:

1. Farmer protection from liability must be provided under federal law if pesticides have been lawfully applied. Specifically, we want to make sure that farmers will not be held liable under federal law for such things as having to provide drinking water supplies if farmers have used the pesticide in accordance with EPA approved label instructions.

2. National uniform tolerances for pesticide and herbicide residues must be established. States should not be permitted to establish pesticide residue tolerances different from those established by the EPA.

3. Groundwater protection provisions should strike a balance that provides protection for groundwater resources while ensuring that farmers will be able to responsibly use the necessary agricultural chemicals needed to protect crops.

4. The indemnification provision of current law which provides that a farmer be reimbursed for the value of any unused pesticides in his possession on which EPA suspends or cancels registration must be continued. S. 1516 makes indemnification subject to a special appropriations process by the Congress which will be difficult to achieve on a situation-by-situation basis. The current indemnification provision affords the farmer some financial protection against an arbitrary suspension or cancellation by EPA.

Senator, we believe the four points outlined above to be reasonable and fair to farmers and the public. We, therefore, ask your help in getting these provisions included in S. 1516 during markup by the Senate Committee on Agriculture, Nutrition and Forestry.

Sincerely,

Bob

W. B. JENKINS
President

WBJ/msp

The **Chairman**. I know that Senator Kassebaum also has a very tight agenda. Are there any other questions for Senator Kassebaum before we continue?

Senator **Cochran**. Mr. Chairman.

The **Chairman**. Senator Cochran.

STATEMENT OF HON. THAD COCHRAN, A U.S. SENATOR FROM MISSISSIPPI

Senator **Cochran**. Mr. Chairman, while I have an opening statement which I will ask to be made a part of the record, let me just add a special welcome to Senator Kassebaum. While I am not a cosponsor of her bill that she described for us this morning, I think we do need to give it very careful consideration. She is about the most respected Member of the Senate, in my opinion, and when she suggests a change that is as important as this one, I think it merits very careful review and thoughtful consideration by our committee.

So I will be one of those who will be reviewing it carefully. I do not know whether it should be included in S. 1516 or not, but I do think we ought to carefully review it. I thank her for taking time to come discuss it with the committee this morning.

Thank you.

[The prepared statement of Senator Cochran follows:]

Prepared Statement of Hon. Thad Cochran, a U.S. Senator From Mississippi

Mr. Chairman, I would like to welcome the participants in today's hearing. The FIFRA Amendments of 1987, on which we are receiving testimony today, are based, generally, on the bill that the House of Representatives passed last October. The provisions in that bill and in the Senate bill considered last year contain historic compromises balancing the interests of the groups represented here today.

I hope that we can continue the unfinished business of reauthorizing and strengthening FIFRA without allowing all of the delicately crafted compromises to fall apart. I also realize that we can't leave out all the remaining controversial provisions just for the sake of having a bill.

For example, one of the provisions that is not a part of S. 1516 is a national pesticide residue tolerance system. Since we have a nationwide market for most foods, it is critical that we have a national pesticide residue tolerance system. This system should be without regard to State or county lines, in order to assure orderly marketing and maintain public confidence in the wholesomeness of the food supply.

I appreciate the contributions of our witnesses today toward developing a sane, workable legislative package.

Senator **Kassebaum**. Thank you very much, Mr. Chairman.

The **Chairman**. You have gotten all these endorsements.

Senator **Kassebaum**. That is right.

The **Chairman**. We will leave the record open for further endorsements of Senator Kassebaum.

Senator **Kassebaum**. But there is a little caveat there where maybe it should be considered at another time. Thank you very much, Mr. Chairman. I do know that this is an important subject. And I value the opportunity to testify.

The **Chairman**. Thank you. I must admit, and I think Dick might join me in this, that it is so nice to see so many people in the Senate interested in and knowledgeable about FIFRA. I think the two of us felt awfully lonely back in 1978 as we tried to find somebody to talk to about FIFRA. And they would say, are you stuttering or what? Thank you very much.

Senator **Kassebaum**. Thank you.

The CHAIRMAN. I notice that Congressman Mike Synar is here from Oklahoma, and Congressman, we are delighted to have you here. You are the chairman of the Subcommittee on Environment, Energy, and Natural Resources. And again, one of those who actually understands this subject. Glad to have you here, Mike.

The prepared statement of Senator Karnes is received for the record.

[The prepared statement of Senator Karnes follows:]

STATEMENT OF HON. DAVID K. KARNES, A U.S. SENATOR FROM NEBRASKA

Mr. Chairman, I am pleased to be able to participate in these hearings today. I look forward to learning more about the many wide ranging issues involved in the Federal Insecticide, Fungicide, and Rodenticide Act.

I feel certain a vast majority of our citizens do not realize the potential impact this issue has on their health, the quality of their environment, and on their businesses. This is due in large part to the fact that the subject of FIFRA is a highly technical, complex issue and one which, by its very nature, is not conducive to generating a great deal of everyday discussion by the average citizen.

I feel it is significant that FIFRA legislation is structured in terms of risk and benefit. I believe a balanced risk/benefit approach is proper and we must keep this concept in perspective as we debate and develop this legislation. I also believe we must develop proper balance in terms of assuring producers of agricultural products covered by this legislation access to products at the lowest possible cost while not restricting in any way continued development of new products to address new problems in the most efficient, effective manner possible.

I look forward to hearing from the witnesses today and appreciate the opportunity to be able to have the benefit of their knowledge and viewpoints.

Thank you, Mr. Chairman.

STATEMENT OF HON. MIKE SYNAR, A REPRESENTATIVE IN CONGRESS FROM THE THIRD DISTRICT OF OKLAHOMA

Mr. SYNAR. Thank you, Pat. I want to thank you for the opportunity to comment on your efforts to amend FIFRA. On two occasions I have testified before the House Agriculture Committee about numerous pesticide program improvements I strongly believe are needed. My recommendations have been based largely upon the results of investigations conducted by the House Subcommittee on Environment, Energy, and Natural Resources, which I have the honor to chair.

Our investigations in 1983 and 1984 uncovered some very serious weaknesses in EPA's registration program—particularly in the area of special reviews and reregistration activities. Inordinate delays, bureaucratic foot-dragging, and an inability or unwillingness by Agency officials to make final decisions had stagnated the program and thwarted congressional intentions to ensure that pesticides presently on the market are safe and acceptable for use. We are all painfully aware of EPA's limited progress to date in this area and the magnitude of effort which remains ahead.

I am pleased that these concerns have been addressed in the FIFRA reform packages again under consideration in both bodies. I believe that key provisions in both the House and the Senate bills—accelerating pesticide safety reviews, collecting registration fees, and streamlining cancellation procedures—will all contribute invaluably to the efforts to reestablish the congressional objectives iniated in 1972. The bottom line here is that action must be taken to improve protection for our farmers, consumers, and environment from the widespread application of pesticides which remain on the market today without adequate proof of their safety.

Let me also, for the record, reaffirm my support for the inclusion of provisions relating to ground water protection, citizens' right-to-know, and public participation. As we begin once again the process which we nearly completed in the 99th Congress, there are obviously a number of highly contentious issues left unresolved from last year's debate.

I am very concerned, however, and the reason I am here this morning, and the reason I wanted to take a little bit of your time, is on one particular issue that has not been adequately addressed. I am referring to the question of who pays the costs for indemnification and disposal of banned pesticides. Mr. Chairman, I firmly believe that this one issue will have a larger impact on the success of pesticide reform than any other provision currently under discussion. I think it deserves thorough and comprehensive consideration by both bodies.

Last November my subcommittee held hearings to review EPA's efforts to dispose of EDB. As you know, EDB was first suspended in 1983. To this day in 1987, none of the remaining EDB stocks have been disposed of. Our investigation found that manufacturers have been paid literally millions of dollars in taxpayer money for products that no longer exist because they have been improperly stored and have been leaked into the environment. Clearly, indemnification does not provide any assurances that banned products will be handled safely or disposed of properly.

Earlier this month my subcommittee held a hearing to again review EPA's progress on EDB disposal and to examine the broader policy issues of indemnification for the disposal of all banned pesticides. Here is what we learned. The original EDB disposal cost estimates are a fraction of what the ultimate costs will be. EPA indemnification and disposal costs for the canceled pesticides EDB, 2,4,5-T, and silvex have already reached $30 million, and completing these tasks for just those three plus the suspended pesticide, dinoseb, may well cost the taxpayers another $200 million. Experience suggests that these estimates, very frankly, may be underestimated.

Where are these funds coming from? These costs are being paid from pesticide program funds allocated for registration and other pesticide safety activities. The net result is that the indemnification and disposal responsibilities under current law are constraining EPA's ability to conduct the pesticide safety reviews. Inevitably, the costs of indemnification and disposal will weigh inequitably in the minds of EPA's decisionmakers when they are considering possible suspensions or cancellations.

Our recent hearings also demonstrated that indemnification is a manufacturers' issue, not a farmers' issue. Let me repeat that. It's a manufacturers' issue, not a farmers' issue. Plain and simple, indemnification is a federally subsidized insurance policy for pesticide producers. Experience shows that when a pesticide is suspended, manufacturers and/or registrants generally recall their products, compensate their customers and consolidate their indemnification claims to EPA. Chevron has received $12.8 million, or 70 percent, of the 2,4,5-T/silvex indemnities. Uniroyal will receive the lion's share of indemnities for dinoseb, perhaps as high as $20 million or more. These are enormous subsidies to enormous corporations. Furthermore, the pesticide producers have long known the data submission requirements for reregistration. They know the rules of the game. If producers continue to market pesticides that have not been reregistered and do not have scientific studies to support reregistration, they do so at their own risk. Producers should not be shielded or indemnified for these business risks.

Mr. Chairman, I am pleased to see that S. 1516 makes some changes in the indemnification program. However, the bill does not go far enough because it still relies on the taxpayer to pick up the tab for the pesticide manufacturers. I believe it is time to relieve the taxpayer of this burden and place the responsibility at the doorstep of those who have long profited from the sale of these products, the chemical manufacturers. I would, therefore, urge your committee to repeal section 15 on indemnities. In addition, I would urge the committee to restructure EPA's disposal responsibilities. EPA should have clear authority to monitor the storage and disposal of banned pesticides, but the cost should be borne by manufacturers, not the taxpayers.

Again, let me thank you for the time, and I look forward to working with committee members, as well as the House, toward a resolution of this important issue.

The CHAIRMAN. Thank you very much. Let me ask you, do you have a feeling for the time schedule in the House on FIFRA legislation?

Mr. SYNAR. It is hard to say, Pat. I think that we are trying to get it through maybe the first week after we get back from the recess. Obviously, that is our intention. One of the things that we are having a problem with is that there is some fear out there that there will be a tremendous amount of amendments because of certain issues that have not been resolved.

The CHAIRMAN. Thank you very much.

Senator LUGAR. Congressman, do you have any given idea, from your own experience, and your own hearings, potential costs with regard to banned pesticide disposal in the instances you have cited? Does this survey the entirety of what FIFRA encompasses? Has your committee, or from any other resources, do you have ideas of the type of incident of costs that might be faced either by the taxpayers, the manufacturers, or some combination?

Mr. SYNAR. Dick, we do not have an estimate on that because we do not know how many will be banned, canceled, or suspended. But let me give you the three we did. For 2,4,5-T/silvex, the cost to date has been $25 million. EPA estimates $3.5 million in additional funds will be needed.

For EDB, we have spent $4.5 million to date. We are expecting $10 million of additional costs. For dinoseb, we have not spent a penny yet, but EPA conservatively estimates that could be $60 to $120 million. So we are talking in the neighborhood of $200 million for just the first three. So if you put that in proportion to the potential ones down the road, this could literally be billions of dollars depending on how many pesticides we are talking about.

What I am trying to say is that we put our manufacturers of these chemicals in a favored status. You know the FDA when they pull food products off the market, or when a pharmaceutical is pulled off the market, that manufacturer bears the risk. He pays the cost of pulling it off the market, reimbursing the consumer and disposing of it.

I do not see any reason why, if the pharmaceutical industry or the food industry is under that same standard, we should not apply it to the FIFRA legislation. But I think you make the point in your question. Whatever we lose by indemnifying all these chemical companies, that is the money we are stealing from the safety and reregistration programs we need to protect the citizens of our country.

Senator LUGAR. Indeed, we have a problem, and we admitted this in our initial submission of the bill, not knowing how we are going to fund what we all acknowledge EPA must try to do. That is one reason that in the House and the Senate both of us are trying to push down the timeframe in which these examinations occur of chemicals. It could extend on into the next century, we have found, and even then we are not certain how that will be paid for.

We are looking at registration fees. We have tried to obtain some new revenues, but there still is a very sizable gap.

Mr. SYNAR. There will be more money for that if we eliminate the indemnification program.

Senator LUGAR. Indeed. If the indemnification moneys then cancel out what was our initial idea, trying to move along this process, why we have another funding problem of some sort or no progress.

Mr. SYNAR. That is correct.

Senator LUGAR. By EPA or little progress.

Mr. SYNAR. Absolutely.

Senator LUGAR. Thank you.

Senator MELCHER [presiding]. Mike, as I understand your testimony, you would just strike all indemnity?

Mr. SYNAR. That is correct. I would put them under the same status as pharmaceuticals or food manufacturers on products that are withdrawn because they are found to be a problem, and we make them pick up the cost, as we feel it is part of the risk of doing business. They have known all along that that was part of the risk.

Senator MELCHER. Thank you. Senator Breaux.

Senator BREAUX. Glad to have Mike here. He has always been a leader in these areas in the House. What is the effect if we do away with section 15? What do you think the effect would be on the marketplace?

Mr. SYNAR. Well, I think the effect John, would be that the $200 million that is required for indemnification would eat up the entire budget for the reregistration that we have tried to accelerate, as Dick has mentioned. If it gets all eaten up in indemnification, we put ourselves even farther behind on the real purpose of FIFRA which is to move these things forward.

The other effect is, very frankly, to put chemical manufacturers in the same status as food manufacturers, pharmaceutical companies and others.

Senator BREAUX. Thank you.

Senator MELCHER. Senator Daschle.

Senator **Daschle**. Thanks, Mr. Chairman. Mike, that was an excellent statement. I have a couple of questions with regard to your recommendation on section 15. Is the approval process under FDA and other Federal agencies for food and pharmaceutical products the same as it is for EPA with regard to chemicals?

Mr. **Synar**. Is what process?

Senator **Daschle**. The approval process. In other words, the way in which these products are put out to the market, is that analogous to food and pharmaceuticals?

Mr. **Synar**. Tom, I do not know the specifics. I have and will submit for the record the response we received when we asked that exact question. We asked FDA to give us the system by which they do the approval, and also the pulling off, so that we could get a kind of comparison, and we will provide that for the record because I think that is important.

[The material follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 6, 1987

The Honorable Mike Synar
Chairman, Subcommittee on Environment,
  Energy, and Natural Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Synar:

This is in response to your letter of June 25, 1987 requesting information on the Food and Drug Administration's (FDA) regulatory procedures and experiences.

The following are our responses to your questions in the order they were presented in your letter:

1. FDA carries out the responsibilities assigned to it by Congress under authority of several statutes. The four laws which form the statutory basis for the majority of FDA activities are the Federal Food, Drug, and Cosmetic (FDC) Act; the Fair Packaging and Labeling Act; the Radiation Control for Health and Safety Act; and the Public Health Service Act.

The provisions of these laws are intended to ensure that (1) food is safe, wholesome and produced under sanitary conditions; (2) drugs (both human and veterinary), biological products (e.g., vaccines and blood and blood components), and medical devices are safe and effective for their intended uses; (3) cosmetics are safe and made from appropriate ingredients; (4) the use of radiological products does not result in unnecessary exposure to radiation; and (5) all of these products are honestly and informatively labeled. We are enclosing a publication entitled Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration and a copy of our employee orientation handbook entitled All About FDA which provide further information on FDA's responsibilities and activities.

2. FDA acquires information on violative products in most cases from:

- -- FDA inspection of firms
- -- analysis of product samples
- -- notification from responsible firm
- -- consumer and trade complaints
- -- cooperating Federal, State, and local regulatory agencies
- -- adverse reaction reporting system via physicians and pharmacists

The enclosures described above provide additional information in this area.

3. There are several regulatory procedures available to FDA when the agency discovers that a product is unsafe or otherwise unfit for public use or consumption. Products may be voluntarily destroyed, field corrected or recalled from the market by the responsible firm, or they may be seized by U.S. Marshals on orders obtained by FDA from Federal District courts. Responsible firms or persons may be prosecuted in the Federal courts and if found guilty may be fined and/or imprisoned. Continued violations may be prohibited by Federal court injunctions. Any or all types of these procedures may be employed, depending on the circumstances. The enclosures described above provide additional information on FDA actions.

4. Manufacturers bear the responsibility for recalling their products from the market place. Although FDA does not have legal authority to require a firm to recall a violative product, FDA may request a firm to initiate a recall when certain conditions have been met. To provide you with detailed information on the manufacturer's responsibilities during a recall, we are enclosing the following:

-- Food and Drug Administration Enforcement Policy Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities, which was published in the Federal Register on June 16, 1978.

-- Title 21 Code of Federal Regulations (CFR), Part 7, Subpart D - Infant Formula Recalls

-- Methods for Conducting Recall Effectiveness Checks which was prepared by FDA to provide guidance to firms conducting recalls.

5. FDA does not have specific legal authority to ensure that product recalls are properly conducted. However, the Agency has specific procedures to assure consumer protection during a recall. FDA's Regulatory Procedures Manual (RPM) Part 5 (copy enclosed) discusses FDA's operational policy and procedures for all recall actions. The Federal Register and CFR described in number four above also provide information on FDA's recall policy and procedures.

6. The responsible firm bears the financial burden resulting from product recalls and disposition. An instance in which FDA bears the financial burden of a recall is when the firm responsible for a violative product is out of business and consignees must be notified. Another cost to FDA resulting from a recall is FDA's performance of audit checks which determine the effectiveness of a firm's recall.

7. The FDC Act permits with some exceptions the exportation of products which would be illegal in the United States if these products

(1) meet the specifications of the foreign purchaser, (2) are not in conflict with the laws of the foreign country, (3) are labeled on the outside of the shipping container that they are intended for export, and (4) are not sold or offered for sale in domestic commerce. Medical devices and unapproved human and animal drugs must meet additional requirements before they can be exported.

8. We are enclosing three charts which provide the number of recalls which occurred in Fiscal Year 1985, Fiscal Year 1986, and the first half of Fiscal Year 1987 by classes (which are defined in the enclosed RPM) and by Centers.

Our experiences with product recalls have generally been good. FDA has rarely found recalls to be ineffective. We have determined from our experiences that the length of time needed to remove a product from the market varies with each recall because it is dependent on the quantity of product recalled, when it was distributed, the extent and level of distribution, meaningful coding or identification, brands, and the type of product and problems associated with it.

We hope this information is helpful. If we can be of further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

NUMBER OF RECALLS BY CLASS AND CENTER FOR FY '85

CENTER	CLASS 1	CLASS 2	CLASS 3	TOTALS
DRUGS	1	278	173	452
AND BIOLOGICS	0	23	8	31
FOODS	207	601	171	979
DEVICES AND RADIOLOGICAL HEALTH	31	420	133	584
VETERINARY MEDICINE	1	21	17	39
TOTAL	240	1343	502	2085

NUMBERS OF RECALLS BY CLASS AND CENTER FOR FY '86
DIST = ALL START DATE = SEPTEMBER 30, 1985 END DATE = OCTOBER 1, 1986

CENTER	CLASS 1	CLASS 2	CLASS 3	TOTALS
DRUGS	6	47	276	329
AND BIOLOGICS	0	39	12	51
FOODS	576	855	371	1802
DEVICES AND RADIOLOGICAL HEALTH	9	633	120	762
VETERINARY MEDICINE	41	76	7	124
TOTAL	632	1650	786	3068

NUMBER OF RECALLS BY CLASS AND CENTER FOR FY '87
START DATE = SEPTEMBER 30, 1986 END DATE = APRIL 1, 1987

CENTER	CLASS 1	CLASS 2	CLASS 3	TOTALS
DRUGS	0	228	42	270
AND BIOLOGICS	0	7	3	10
FOODS	82	365	70	517
DEVICES AND RADIOLOGICAL HEALTH	0	216	81	297
VETERINARY MEDICINE	2	22	3	27
TOTAL	84	838	199	1121

Senator DASCHLE. I think you could make a strong case if the answer to that question is yes. Then I think a case can be made for treating chemicals after they have been relegated to the market the same as foods and pharmaceutical products. With regard to indemnification, obviously we are talking about two issues here. First, the question of indemnification, and second, the question of disposal.

Are you saying that of the funds already provided through indemnification nothing has been used for disposal?

Mr. SYNAR. No. What we are saying is that the money that we pay these manufacturers to pull it off the market and dispose of it, we are paying them, and they are not disposing it.

Senator DASCHLE. That is what I am asking. So none of the funds have been utilized so far?

Mr. SYNAR. EDB, which was pulled off the market in 1983, as of this date has not been disposed of. In fact, we are paying manufacturers that are storing it, and a lot of it has leaked out into the ground. So we are paying them for a product that does not even exist.

Senator DASCHLE. What oversight is there? What requirement is there for this particular company or any company indemnified to utilize these funds with some expeditious process?

Mr. SYNAR. Well, the thing that we found through the hearing process is that EPA has taken the position that it is the company's responsibility to adequately withdraw and dispose of it. What we found in the case of EDB is that the companies are not doing a good job.

One of the things I recommended in my prepared statement is that the EPA has got to develop a stricter enforcement mechanism so that we can protect against this.

Senator DASCHLE. Are there no regulations with regard to timeframe and disposal at this point?

Mr. SYNAR. Well, there are rules and regulations, but when you are relying on the companies to do it, and you are not providing sufficient guarantees. In the case of EDB out in Representative Ike Skelton's district, we are continuing to find storage leaks and EPA has not been enforcing against this.

Senator DASCHLE. Thank you very much.

Mr. SYNAR. Tom, if I could just briefly tell you about the FDA experience. Let me just read you from what they told us in one sentence. Over the past 2½ years, FDA has administered more than 6,000 product recalls. And the Agency noted, when we asked them, "that our experiences with product recalls have generally been good. FDA has rarely found recalls to be ineffective," and they go through and tell us the approval.

Senator DASCHLE. Thank you.

Senator MELCHER. Mike, have you looked at what the cost effect might be in case of repeal of indemnities? I am not talking about the cost to the Federal Government. I am talking about the cost to the product. Have you inquired into what the repeal of indemnity might mean to the manufacturers in terms of their whole cost structure for arrival at a price for consumers?

Mr. SYNAR. Well, that is a hard number to come up with for two reasons. First of all, it would depend on which pesticides are affected and who holds those pesticides. In the cases mentioned in my statement, the major companies, Uniroyal and Chevron, control most of two pesticides that have been removed from the market. They will receive the lion's share of those moneys. Those are not small corporations.

FIFRA and the principle of indemnification were created to help the farmer. I am here to tell you that that is long gone. A manufacturer's guaranteed insurance policy is what this is. It has nothing to do with giving incentives to farmers to pull those pesticides off the market.

So what we are doing basically is subsidizing major corporations who can afford the expense to be in the pesticide business, and it is hard to get a number on that. We do know that costs on those two particular ones would be about $17 million, $12 million of which Chevron is going to get in indemnification, and $20 million for Uniroyal. So that means that they would have to pick up that cost.

That is not necessarily to say that that is going to be exorbitant. The other thing I want to point out is that these pesticides have been on the market a long time. They have made a lot of money. They have paid back their basic initial cost, research, and development. So we are not talking about someone who is going to lose or who is not going to have had their payout on this.

So, we are not hurting them, as they may argue.

Senator MELCHER. I think perhaps indemnity was put into FIFRA with the idea that when there had to be a recall, they wanted the recall to be effective and have efficient, and no profit motive enter into it by just trying to boost out in final days or predating, or what have you, to get rid of the product that might have to be recalled and destroyed.

Since it has been in the law, I feel that perhaps it is part of the cost structure built into the whole mechanism of pricing the product. Has anybody come up with any testimony, study, or any evidence of what the shift might be if it were repealed now?

Mr. SYNAR. They really have not put that in their cost structure because all they had to do is turn to the Federal Government to pick up the cost. The way this thing works is that when a pesticide is suspended, the company draws in the stocks. They reimburse their consumers who have purchased this, and they consolidate all of the stock. Then they wait for the Federal Government to come in and pay them. Then we pay them. They are supposed to pull the product off the market and dispose of it. As we have found in the first three cases of suspensions, they are not disposing of it. And we are paying them in some cases where stocks do not exist.

Senator MELCHER. Has EPA prescribed how it should be disposed of?

Mr. SYNAR. They have rules and regulations basically, but, again, they leave it up to the companies to do their own oversight.

Senator MELCHER. Thank you.

Senator DASCHLE. Mr. Chairman, I would like to follow up because I thought your question was a good one. I am not sure that I understood Mike's answer completely. With regard to indemnification, if the Federal fund is not there, obviously it will be borne by the company.

Mr. SYNAR. Correct.

Senator **Daschle**. The real question is how major would the cost be to the company or to the consumers, who would ultimately pay the cost because it would be passed through to the product? What would be the impact in terms of a percent of the overall cost? If $200 million is the stated anticipated amount for indemnification, how much of the entire pie is a $200 million figure?

Mr. **Synar**. First of all, we do not have those numbers, Tom, and they are very hard to come up with because it depends on how much they paid on the front end in research and development, as well as how much the disposal would cost. If we get a more efficient disposal technique, it will cut down on the cost.

I think the thing that I would point out is that these companies are the first to know when they have a problem because it is their studies that they are submitting to EPA that are telling them that they have some potential problems. So they know about the problems they are facing long before EPA does, and they can basically take that into consideration as we move down this path.

The second thing is that we have to realize they have already made their money back on these pesticides. It is not something that we are taking away from them or taking down from them. They have made their money. Again, we do not have the numbers to determine whether they pass on those costs to future pesticides which they are selling. The point is that this is a favored status given to no one else doing business in this country.

They know the risk of doing business and they know when we started this whole program that this was a potential risk. Pharmaceutical companies do not have this benefit. Food companies do not have this benefit. There is just absolutely no reason why we should put them in this status. No one else has that status.

Senator **Melcher**. Thank you very much, Mike.

Mr. **Synar**. Thank you.

Senator **Melcher**. Our next witness will be John A. Moore, the Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency.

STATEMENT OF JOHN A. MOORE, DVM, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Dr. **Moore**. Senator, I ask that my prepared statement be inserted in the record, and I would like to highlight a couple of items within my prepared statement, as a matter of introducing the subject from EPA's perspective.

Senator **Melcher**. Your entire statement will be made part of the record, and you may summarize it any way you choose.

Dr. **Moore**. Senator, S. 1516, in my opinion, clearly improves upon the bills that were developed last year and fell short of passing in the waning days of Congress. Clearly, the heart, I think, of the bills last year and the heart of the bill this year deals with the subject of acceleration of the reregistration process.

Quite clearly, there are two ways of doing that that are being addressed in the bill. One is to streamline the administrative process that is involved in the reregistration. For example, in the process of getting current registrants of old pesticides to commit to the reregistration process or else get out of the market is enhanced. Our ability to make that come to pass is enhanced with the language that is in the bill as opposed to current statute.

Also the streamlined administrative procedures that are in an administrative review are another example of improvements, I think, over the current statute in that regard. The second main way to accelerate reregistration is to increase the resources available to the Agency in order to get this job done.

It is quite clear that the one time fee provision in S. 1516 goes a long way toward narrowing the gap between the fees that are required and those which were to be generated in last year's bill. I think that is an important step forward because absent the closing of that gap, I think the Agency is doomed to failure before it starts since it just would not have the resource available to meet the deadlines that are implicit within the bill.

Second, there is also some language in the bill that shifts some of the burdens associated with reregistration from the Agency over to the registrant, particularly in the area of reformatting and resubmitting data as a part of this reregistration process.

A point that I think has been addressed nominally in S. 1516 that still needs work is that which was primarily discussed by Congressman Synar just a few minutes ago. We still maintain that section 15 dealing with indemnification should be stricken from the statute. S. 1516 proposes that we would not disburse any money for indemnification unless it was specifically appropriated and earmarked for that purpose by the Congress. That certainly minimizes or eliminates the financial crunch associated with indemnification that we sometimes face currently.

What is not fixed, I believe, is the disposal part of the situation. When a chemical is suspended and canceled, there are four elements that basically have to be accomplished by somebody. One is to identify where those stocks are, who has them and what form they are in.

Second, one has to identify and make sure that there is proper storage pending ultimate disposal. Third, one has to identify what disposal technology is to be used in order to eliminate those materials, and then last is the actual job of collecting those stocks and performing the disposal technology.

Currently, by law EPA has the responsibility to do all of those items. There is a distinction between disposal and indemnification. Indemnification is roughly one-half of the problem or the financial burden that is associated with a suspended and canceled pesticide. EPA must pay the holder of the stock the cost that he or she has incurred in the development of that material. The second half of the cost is associated with the storage and then ultimate disposal of the material.

By the very nature of the suspension action, it is an unbudgeted resource. We cannot tell you when the next chemical is going to be suspended. As Congressman Synar has pointed out, the costs associated with storage and disposal are in the multiples of tens of millions of dollars. We also have a problem within the Agency as far as having an adequate skills mix to develop the technology and then oversee the physical disposal of material, as well as having limited authorities regarding our ability to enforce our regulations dealing with storage and disposal.

S. 1516 does attempt to make our regulations enforceable in this area. I think the other question, aside from the financial one, is whether our role should continue to be to have the total responsibility for storage and disposal of the materials, or whether our role is more properly what I consider to be the more traditional regulatory role, that of oversight of proper storage and disposal in this case.

I hope that the Senate will give serious consideration to section 19, particularly of the current FIFRA. In closing let me comment on tolerances. As this committee knows, the National Academy of Sciences published a report dealing with tolerances and pesticides.

We still feel that the major recommendations in that report have great merit. These are a uniform approach to the setting of tolerances or residues as a consequence of pesticide use and the employment of the concept of negligible risk in the setting of those tolerances. I would like to move forward with those types of recommendations. I do think the current statute makes me fairly vulnerable legally should I intend to try to move forward in that area. I would be glad to answer any questions you might have.

[The prepared statement of Dr. Moore follows:]

STATEMENT OF
JOHN A. MOORE
ASSISTANT ADMINISTRATOR FOR PESTICIDES
AND TOXIC SUBSTANCES
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION,
AND FORESTRY
UNITED STATES SENATE
JULY 30, 1987

Good morning, Mr. Chairman and members of the Committee. I appreciate this opportunity to discuss S.1516, the "Federal Insecticide, Fungicide, and Rodenticide Act Reform of 1987," and S.1419, the "Ground Water Safety Act of 1987."

During the past year certain pesticides issues have assumed greater significance than ever before. Chief among these are disposal and indemnification. In commenting on these new bills I will particularly focus on how effectively they deal with these issues.

DISPOSAL AND INDEMNIFICATION

FIFRA currently requires that if a pesticide product is suspended and cancelled, EPA must indemnify the holder of such a product and accept it for disposal at federal expense. However, FIFRA provides the Agency no instructions to carry out these responsibilities.

Agency regulatory actions suspending and cancelling 2,4,5-T/silvex and EDB products, and suspending and initiating cancellation of dinoseb products, have brought the inherent statutory problems to a head.

Since last fall, the Agency has devoted significant resources and time to the management of these problems. There have been major changes within the limited scope of our current authority.

There still are complex issues, however, which require resolution. Problems are associated with each of the major responsibilities in disposal and indemnification. Under current law the Agency has three major responsibilities associated with with disposal.

1) Developing Disposal Technology: The disposal technology for a chemical frequently is not known at the time of suspension. Therefore, effective disposal methodologies have to be developed by EPA and appropriate plans for implementation devised, all at EPA expense.
2) Ensuring Proper Storage and Transportation until Final Disposal: This includes identifying stocks, maintaining safe storage pending final disposal, and inspecting storage sites. The Agency is currently conducting inspections under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). CERCLA authority provides the potential for enforcement actions and penalties for violators, which FIFRA can not provide.
3) Actual Disposal of the Product. This responsibility includes locating and contracting with private firms capable of conducting the disposal operation, securing necessary state and local permits, and overseeing the final disposal process.

> The traditional expertise of the Office of Pesticide Programs is not well suited to these tasks. It is, in fact, the pesticide industry which is best equipped to deal with these technical issues pertaining to their products.

The Agency's ability to conduct the process is hampered by the FIFRA itself. The FIFRA provides the Agency with little enforceable authority over storage or disposal of pesticides once the suspension and cancellation orders have been issued. While the regulations issued under FIFRA provide some guidance for the storage of suspended pesticides, compliance with them is not generally mandatory or enforceable under the statute as written. Furthermore, the state and local permitting process and efforts to find an appropriate site may be long and complex. Community concerns play an important role as well.

Impact on Program

Together, the impact of indemnification and disposal activities on the Agency has been and will continue to be ficant. Although the total information necessary to make complete estimates is not yet available, current estimates indicate that it will cost an additional $2.2 million to complete only the most critical disposal activities in fiscal year 1987 -- or by October 1, 1987.

This fiscal year, my office has expended $1.3 million of fiscal year 1987 appropriations for indemnification and disposal purposes; $878,000 from my budget and $380,000 from another part of the Agency.

Additional funds are being committed at the rate of $120,000 each month. These costs are only for the de-canning of EDB stocks into rail cars pending disposal.

This of course is in addition to the amounts the government has already paid. For indemnification only, the amount paid for 2,4,5-T and silvex was approximately $20 million. The current amount which has been paid in processing and funding indemnity claims for EDB is $2,800,000.

In summary, the disposal and indemnification of suspended and cancelled pesticides presents several significant problems. These must be addressed if EPA is to effectively manage the specific actions now in progress and develop an overall management strategy for the future.

As long as these problems remain, storage and disposal of these pesticides may pose environmental and human health risks of the very sort the Agency hoped to prevent by suspending and cancelling their registrations.

Our position on disposal remains consistent--it is a cost that should not be borne by the federal government. Furthermore, even if there is merit to the government assuming oversight responsiblity for proper storage, the industry must make resources available. S.1516 would give the Agency the ability to issue enforceable regulations governing disposal of pesticides which we support.

Our position on indemnification is also clear. It should be repealed. The government should not be in the position of insuring the pesticide industry.

RESOURCES

S.1516 contains a reregistration provision which represents a significant improvement over the fee provisions in last year's legislative proposals and H.R.2463. We estimate that it would result in revenue of approximately $113 million over a five year period. To accomodate those registrants who truly may not be able to afford the fees envisioned in S.1516 the Agency could use its existing authority under FIFRA 25(b) to waive the fee requirement.

This increased revenue through the fee is essential to the success of the ambitious reregistration program that S.1516 would mandate. It comes much closer to matching resources to the demands of the numerous deadlines in S.1516, though we estimate revenue from such fees would still be short by $30-40 million for fully funding accelerated reregistration. Without this kind of fee provision the Agency would be doomed to failure before it even began the tasks outlined in the bill. However, the fee should be raised to fully fund the accelerated reregistration program.

TOLERANCES

The next issue I would raise concerns the reassessment of pesticide tolerances. I have recently testified before this Committee specifically on this topic so I will keep my remarks brief today. Tolerances are established under the Federal Food, Drug and Cosmetic Act (FFDCA) rather than the FIFRA. The two statutes are not, particularly in the case of oncogens, easily reconcilable. For new chemicals, the Agency has been applying the Delaney Clause of the FFDCA rigorously. In the case of old chemicals, the Agency, through the reregistration process, is identifying a number of specific pesticide uses which highlight the differences between the two statutory standards.

With the issuance of the NAS report, Regulating Pesticides in Food: The Delaney Paradox, in May the Agency now has a set of reasonable, sound recommendations to guide the course of tolerance reassessment. The report deserves detailed study and discussion by EPA and other concerned agencies as to the specifics of implementation. We have in fact begun this process and will be issuing a specific implementation plan for public comment in September.

In particular, we favor the use of a "negligible risk" standard in the regulation of pesticide residues. Under such a standard, a pesticide would be presumed approvable if its risk is negligible, considering the full weight of the evidence; a greater-than-negligible risk would have to be clearly outweighed by the benefits.

REREGISTRATION

The Agency has devoted increased attention to its reregistration program. By the end of last year, the Agency had evaluated data bases and issued registration standards for 127 of the 600 pesticide active ingredients subject to reregistration; today over 160 standards involving almost 9,100 products have been completed. As a result, all product registrations have either been cancelled or suspended for 14 chemicals (aspon, BKLF1-2, carbofhenothion, cycloheximide, demeton, dialifor, fenaminosulf, flucholorin, monuron, monuron TCA, perfluidone, potassium iodate, EPN, and thioprianate ethyl). In addition, for two pesticides (metolachlor and fosetyl-al), the Agency has completed the evaluation of data received in response to initial registration standards and has issued revised standards, and we consider them reregistered.

The Agency has been considering ways to improve the process. There are three basic steps in completing the reregistration of any pesticide:

1) The registrant develops and submits to the Agency all data needed to evaluate the pesticide.
2) The Agency evaluates those data, determines what changes must be made in the terms and conditions of existing registrations, and requires the registrant to make corresponding changes in the composition, packaging or labeling of products containing the pesticide so that they meet the "no unreasonable adverse effects" standard of FIFRA sec. 3(c)(5).
3) The registrant complies with these required changes so that the products available to users fully reflect the results of the reregistration process.

Currently there are steps in the process, particularly the development of an initial registration standard, that are done by the Agency before the registrant begins any work. S.1516 would eliminate that step by shifting much of this early work to the registrant.

In addition we believe that it is critical for registrants to make decisions now, not some five or ten years hence, either to support their product registrations or to remove them from the market. The Agency is consciously using its data call-in authority to eliminate the "free ride" some registrants have enjoyed at the expense of public safety and environmental well-being. As a result, by June 1987 about 8,100 registrations have been cancelled or suspended as a result of data call-in action. Through June this year, 80 chemicals covering 950 registrations have gone off the market (either suspended and/or cancelled) because of data call-in actions. S.1516 incorporates this early decision making concept into the FIFRA itself and by doing so would eliminate much of the administrative burden the Agency now bears under current law. This type of efficiency is key to accelerating reregistration.

We support this new approach because it would enable use to focus our resources on those tasks which only EPA can do--the review and reregistration of pesticides. It would achieve two basic goals: 1) accelerating the generation of data needed to evaluate old chemicals and thereby causing current registrants to commit formally to reregistration or to stop marketing their products, and 2) focusing Agency resources on the earlier evaluation of chemicals with complete data bases or for which potentially adverse effects have been identified.

INERTS

S.1516 also includes a provision on inerts. We have already begun implementing an inerts strategy using existing authority which we believe is sufficient and makes additional legislation in this area unnecessary. We also do not support the deadlines that the bill would impose.

In particular the Agency has categorized the 1200 inerts into four groups: 1) inerts of toxicological concern (List 1); 2) potentially toxic inerts/high priority for testing (List 2); 3) inerts of unknown toxicity (List 3); and 4 inerts of minimal concern (List 4).

Our initial regulatory efforts are focused on the List 1 inerts of toxicological concern. Registrants of products with inerts on List 1 are encouraged to substitute with an inert ingredient not included in List 1 or 2. Those with inerts on List 1 who do not substitute must label their product to identify the inert of toxicological concern by October 1988. In addition, these registrants will receive data call-in notices requiring the development of exposure data and any additional toxicity data needed. We expect to issue data call-ins for the first 8 inerts by the end of the fiscal year. The pace of future call-ins will be determined by our experience with the first 8.

For some of the inerts on List 1 the Agency also intends to hold FIFRA 6(b)(2) hearings. The purpose of these hearings will be to gather and present information on risks and benefits. Based on the hearing record, the Agency will decide whether products containing these inerts should be cancelled, subject to additional restrictions or allowed to continue their registration unchanged. We expect to begin the first hearing this fall.

We have also identified 5 inerts from List 1 that we believe are better classified as active ingredients because they are present in pesticide formulations to act against some pest that may attack the product itself. EPA has already proposed to reclassify formaldehyde and paraformaldehyde as actives when they are used to prevent microbial damage to pesticide products and the Agency is now analyzing comments on the proposal. Reclassification will result in identification of the substance on product labels and simplify the process of obtaining necessary data.

For inerts on List 2, the Agency's goal is to collect enough information on each to determine whether further regulatory actions like those for inerts on List 1 are necessary.

With regard to new registrations of products, the Agency generally is not approving new products containing a List 1 inert unless they are identical or substantially similar to existing products. Such new products are subject to the regulatory actions just described for List 1 inerts including listing on the product label. Identical or substantially similar products containing List 2 inerts are also being registered. Decisions regarding new uses of List 2 products are made on a case-by-case basis. As noted last year, the Agency now also requires a minimum data set to evaluate all new inert ingredients and new food uses of existing inerts.

At this time, the Agency is not taking any particular regulatory action involving inerts on Lists 3 and 4, with the exception of evaluating proposed new uses of such ingredients. As the Agency deals with the chemicals on Lists 1 and 2, it will extend its efforts to these other inerts.

CERTIFICATION AND TRAINING AND PROFESSIONAL APPLICATOR REGISTRATION

Increasingly, the Agency is adding label restrictions to pesticides as well as classifying more pesticides for use by or under the direct supervision of certified applicators in order to reduce risks while maintaining the needed benefits of particular pesticides. Of the registration standards issued in fiscal year 1986 and 1987 to date, 16 active ingredients were restricted (ten for the first time and six reaffirmed from previous decision making). Restrictions, however, are only effective if we can reassure the public that persons using these materials are well-trained and competent to use these materials in strict compliance with the label. When I testified before you last year, I mentioned the recommendations that the State/EPA Certification and Training Task Force had made to strengthen the certification and training program, the need for EPA to have flexibility on setting the appropriate level of supervision a certified applicator must exercise under varying circumstances of use and differing pesticide properties, the need for verifiable training and registration of commercial pesticide applicators, and the ability of EPA to require examination of private applicators after training to establish competence.

Since then, the Agency has aggressively pursued many of these recommendations administratively, working closely with our USDA and state colleagues and many user organizations. We have finished an in-depth review of all state certification plans and are now working with individual states to update their programs.

Also, we have initiated a process to revise the regulations which implement FIFRA certification provisions. I believe that those regulations, now almost 10 years old, are basically sound but need upgrading to meet the requirements of changing technology, and to provide for greater consistency among states in assuring competency of certified applicators.

In the President's fiscal year 1988 budget proposal, the Administration is seeking over a $1 million increase in grants to the states for certification and training which we expect will assist in meeting the challenges of the program.

One concept which has been investigated, is the need to require each person who commercially applies any pesticide to be trained and registered by a state. Several states have already adopted such requirements. The present certification provision of FIFRA applies only to those persons who apply or supervise the application of restricted use pesticides and does not include technicians or others working under their supervision. I believe that the concepts contained in S.1516 for certification, training and recordkeeping for commercial pesticide applicators respond to this concern with two notable exceptions. First, I do not believe that the training of a person automatically translates into competence unless there is a clear authority for testing. Second, I believe, that to be most effective over time, the Agency should have discretion through rulemaking to adjust its certification and training requirements to emerging technologies and special needs. I should add that over the past year there has been an extraordinary level of cooperation from a number of user groups with EPA, the states and Extension Services, to develop and deliver quality pesticide training to those who are employed by their industry. However, it would be useful not only to upgrade training but also to ascertain the competency of the trained individual.

Nearly 30 states, on their own initiative, require testing for initial certification of private applicators and 37 states already give reexaminations at least as an option to training for recertification. I would like to encourage other states to impose appropriate testing requirements for private applicators and to allow EPA to test in the states in which the Agency runs the certification and training programs.

FARMWORKER SAFETY

S.1516 includes a provision that would compel the promulgation of farmworker safety regulations. The Agency is working on such regulations right now, revising the existing Worker Protection Standards for Agricultural Pesticides published in 1974 and believes that no additional legislation is necessary. The revised regulations would provide broader and more comprehensive coverage to workers, enhance the enforceability of the provisions, while providing protective features at reasonable costs to growers. The proposed standards are expected to be published in the Federal Register this fall and should draw considerable comment from interested groups.

During the past year, the farmworker safety program has published and distributed widely a safety manual for non-certified pesticide mixers, loaders and applicators. This manual complements the early safety manual developed for field workers which has been used in training programs throughout the country. In addition, a large multi-colored poster on personnel protective clothing requirements was developed, in conjunction with NACA, and distributed widely by NACA, USDA and by EPA.

A Pesticide Farm Safety Center has been established at the University of California, Davis, California. A ten person advisory panel to the center has been formed and met for the first time in April. The panel is made up of nationally known technical experts, state representatives and farmworkers. (The center will work on issues such as research, training and information system projects on pesticide safety.)

GROUND WATER

The Agency is conducting a number of ground water activities under existing authorities and believes that the FIFRA provides us with great flexibility to protect ground water. These activities include extensive efforts to gather data needed to assess the problem, and to reach appropriate regulatory decisions. Some of our major efforts include:

1. Agricultural Chemicals in Ground Water Strategy

EPA has just issued its proposed strategy document mapping out the Agency's approach to regulating pesticides which have the ability to reach ground water. It covers such issues as the goal for protection, what waters to protect, and the federal and state roles for achieving the goal. The Agency has also held its second national conference to discuss these issues just last week. We will broaden the opportunity for public comment shortly based on the advice and suggestions offered at this second conference.

2. National Pesticides in Well Water Survey

In addition to the strategy, the Office of Pesticide Programs and the Office of Drinking Water are implementing a survey to estimate the national level and distribution of pesticide residues in community system and rural domestic wells, and to assess the relationship between hydrogeologic characteristics, agricultural use of pesticides, and residues in well water. It will look for about 60 pesticides plus their metabolites and nitrates which EPA believes could leach from normal agricultural use. We have completed a pilot survey in the States of California, Minnesota, and Mississippi this month and plan to proceed with the full survey thereafter. Health Advisories for the pesticides involved in the survey are in the final stages of review and will all be issued by September.

3. Registration

All new pesticides now coming on the market to be used outdoors are carefully examined for their potential to leach to ground water. Each pesticide is regulated accordingly. The Agency has rejected the registration of several chemicals for some or all of the uses proposed, or has permitted conditional registration only under carefully monitored conditions. New chemicals coming on the market must be supported by a full complement of environmental fate data.

4. Reregistration and Special Review

EPA required the submission of environmental fate data for approximately 90 chemicals in a data call-in issued in 1984. The short-term (1 year) data are now in for most chemicals, and the Agency is awaiting field dissipation (2 year) studies on a number of these. In addition, through the registration standards process the Agency examines the potential for old chemicals to leach into ground water. The review can result in continued registration with up-to-date data requirements and labeling through registration standards, a more intensive look at risks and benefits through special review, or cancellation of the products' use. A summary of major proposed and final actions which are based in part on the potential to reach ground water include:

- Special Reviews for:
  - aldicarb
  - alachlor
  - cyanazine
  - 1,3-dichloropropene (Telone)
  - carbofuran
- Cancellations and suspensions resulting in part from ground water concerns for:
  - DBCP
  - EDB

5. Rulemaking

The Agency is also developing a regulation specifying the conditions under which it will restrict the use of a pesticide to certified applicators because of ground water concerns. We expect to propose this rule in the spring of 1988.

S.1419, introduced earlier this summer, represents progress over legislative proposals developed last year and retained in H.R.2463. We are encouraged that this bill emphasizes prevention and has moved away from an absolute zero standard for protection. However, the Agency does have concerns about the bill and cannot support it at this time.

In particular, S.1419 would require the establishment of Ground Water Residue Guidance Levels (GRGLs) for pesticides that have potential to leach into ground water, are detected in 3 different locations, or at the request of a state. The bill would generally require the GRGL to be set at the Maximum Contaminant Level Goal (MCLG) unless the MCLG were zero because the pesticide in question was a carcinogen. In that case, EPA may use an MCL provided the risk resulting from all sources of exposure is negligible. If an MCLG has not been set, the GRGL would be established at a level equivalent to an MCLG. For a carcinogen, this level would be zero. It is technically impossible to measure and clean up to a zero level.

The MCLGs are based only on risk assessments and do not include usual risk management considerations. This requirement of the bill suggests that the risks posed by the presence of a pesticide in ground water are in all cases greater than the benefits derived from use of such a substance. EPA could be forced to over-regulate a substance which may provide substantial benefits to agriculture and to the economy when little actual health or environmental risk exists. The bill has a very broad definition of ground water and provides no differential protection based on the use and value of the ground water source. This could prove problematic. The Agency also believes we have adequate authority under FIFRA to regulate pesticide use and impact on ground water.

SAP

Finally, I would note that the authorization for the FIFRA Scientific Advisory Panel (SAP) expires this year in September. The Agency believes that this peer review panel, composed of independent experts, performs a valuable public service. Accordingly we support its continuation and expansion from 7 to 9 members to accommodate the workload currently placed in the SAP.

In conclusion, those issues which the Agency and others identified last year as critical--efficiency in the reregistration and special review programs, inerts regulation, competency of certified applicators, adequate enforcement authority and realistic fee structures remain key issues. New issues concerning disposal and indemnification, ground water, and tolerances have arisen and are being addressed. The Agency has developed strategies to deal with these issues and is moving ahead.

With these comments I conclude my prepared statement. I and my staff are ready to provide any technical assistance you may need in dealing with these issues.

The CHAIRMAN. Thank you very much, Dr. Moore. I want to note my appreciation of the time you and your staff have spent with ours in putting this together, and the time that you and Lee Thomas spent with me and others in preparation for this legislation. Again, you probably realize better than the vast majority of us just how important and also complex this subject is.

Do you think that the committee should go beyond last year's bill in enacting additional FIFRA reform? I am talking about you personally.

Dr. MOORE. Senator, I think the changes that are embodied in S. 1516 are important positive changes to the bills that were considered last year in the area of fees, for example, and in some of the other areas I have highlighted in my prepared statement.

I do think that you have got to go beyond what was in last year's bill in the area of disposal. Last year's bill was essentially silent on disposal.

The CHAIRMAN. If you had to lay out top priorities for FIFRA reform this year what would they be?

Dr. MOORE. Probably disposal, given the financial crisis that I face with current appropriations for the disposal problems that are outlined with respect to dinoseb, EDB, and still 2,4,5-T silvex. Second, would be making sure the resources are available to accomplish the goals of reregistration and the timeframes that are implicit in the bill. And then also correcting, solving the indemnification problem.

The CHAIRMAN. In S. 1516, the fees for some pesticides are significantly increased, and we have attempted to even out the financial burden on companies as opposed to last year's flat fee for all pesticides with mandatory exemptions.

Notwithstanding increased fees, we on the committee are very concerned about minor-use crops and the potential impact on smaller firms. Actually I have a two part question. Do you need additional authority to address these issues, and do we have your assurance that the needs and special aspects of minor-use crops will be fully considered?

Dr. MOORE. Senator, I think we have a track record of trying to be very concerned about the minor-use crops issues. And, indeed, have had a practice of waiving some of the current existing fees in order to get a registration tolerance set in the use of a pesticide on a minor crop.

I think we have adequate ability in the current statute in that language to allow us to use the appropriate discretion in waiving of fees as it relates to minor crop uses.

The CHAIRMAN. How do you do that? Under 25(b)?

Dr. MOORE. Yes, essentially under 25(b).

The CHAIRMAN. If you had mandatory waiver schemes on reregistration, what would be the impact of that?

Dr. MOORE. Well, I think if we had a mandatory scheme, basically we would be in a position of having lost the flexibility of trying to tailor the response to the problems associated with the pesticide and maybe the minor use it is associated with.

The CHAIRMAN. You have testified that the fee schedule in S. 1516 is a big improvement over the House plan, but your estimate is that there is a $30 to $40 million shortfall. That is a little less than $5 million a year. Could you pledge your cooperation and that of EPA in securing these additional funds? I know that Mr. Thomas could ask for the funding.

Dr. MOORE. Yes, Senator, I do think very significant progress has been made in the fee area compared to last year's bill, and as you point out, there is a shortfall. I am not of the opinion, as I sit here today, that the magnitude of that shortfall is devastating from the standpoint of our position on the bill.

I think our final analysis, however, has to come out as to the totality of the bill, and where that shortfall is in relation to the other positive gains that are in the bill.

As you point out, the $30 to $40 million shortfall is over a 9- or 10-year period of time which equates out to some $4.5 or maybe $5 million a year, something, I think, that is quite different than the specter we were facing last year which shortfalls better than double that in this year's bill.

The CHAIRMAN. What is the Agency's estimate for the cost of indemnification in FY 1988 and beyond, and do you think indemnification is good public policy?

Dr. MOORE. We do not have good estimates for indemnification in FY 1988. In our current estimates for indemnification and disposal, the big unknown is dinoseb. We have just closed the books in trying to come up with the actual figures or how much dinoseb is out there that is eligible for indemnification and how big is the problem as it relates to disposal.

Our estimates are $60 to $120 million for indemnification and disposal. We estimate half of that would be for indemnification. Half of that would be for disposal.

The CHAIRMAN. Do you think indemnification is good public policy?

Dr. MOORE. I do not think indemnification belongs in a FIFRA statute. I think the whole section 15 should be stricken.

The CHAIRMAN. Are any other industries given similar benefits by other regulatory agencies?

Dr. MOORE. Not that I am aware of, Senator.

The CHAIRMAN. I use the example of the Department of Transportation recalling an automobile of a major manufacturer because of the defective transmission, but then being required to buy all the transmissions. Does that go beyond the grounds of the usual rhetoric, would you say?

Dr. MOORE. Yes.

The CHAIRMAN. Or is it a pretty good analogy?

Dr. MOORE. It is a reasonable analogy. I think some of the other analogies are to be found in the drug area.

The CHAIRMAN. Thank you. Dick.

Senator LUGAR. Mr. Chairman, Dr. Moore, you have, of course, commented on the indemnification and disposal issues. Earlier you heard testimony by Senator Kassebaum with regard to payments beyond the patent situation. What is your judgment about that? Should we add the Kassebaum bill into this one, leave it alone, or what is going to, in your judgment, either enhance research in the country but fairly compensate people for doing it?

Dr. MOORE. Senator, I think the issue of compensation of data, or patent term, et cetera, is an issue on which the Environmental Protection Agency remains neutral. It certainly is a very legitimate, if not a contentious, issue that needs to be addressed. My own personal view in listening to the dialog that was going on with Senator Kassebaum is that the best analogies that you might be able to find in that regard may well be the drug industry, and what happened when patent term extension in the generic drug thing came into place. Beyond that I have little to offer.

Senator LUGAR. Does EPA have a point of view on Senator Helms' testimony? He is a proponent of national uniform tolerances, which is also an issue that seems to come around each time that we discuss the thing. Do you have any thoughts about that?

Dr. MOORE. Senator, last year we were, I think, successful in saying we would maintain a neutral stance. I see nothing to persuade me this year that I should deter from that wisdom. I can argue both sides.

Senator LUGAR. So you would suggest sort of a jump ball situation for us there?

Dr. MOORE. I think it is an issue that probably, if it needs to be addressed, is most properly addressed by Congress.

Senator LUGAR. Thank you very much.

The CHAIRMAN. Senator Melcher.

Senator MELCHER. Dr. Moore, on indemnification, the EPA only pays indemnification under the current law when found an imminent hazard. Has that been the case on all the pesticides that have been withdrawn since 1972?

Dr. MOORE. No, Senator Melcher. The only chemicals in the main that have been suspended and canceled, which is the requisite for being eligible for indemnification, are the phenoxy acids, 2,4,5-T and silvex, EDB, and then most recently last year, dinoseb. There have been a number of other chemicals that we have either restricted the use or have resulted in the cancellation of their use which by the nature of the process were not preceded by suspension, thereby making them eligible for Government indemnification of cost. Many of the chlorinated hydrocarbon materials that were canceled fit into that category where the Government bore no indemnification expense.

Senator MELCHER. Bore none.

Dr. MOORE. Bore none.

Senator MELCHER. Does the term "imminent hazard," the finding of imminent hazard, by the EPA trigger all the indemnification payments?

Dr. MOORE. One basically has to make an imminent hazard finding in order to suspend a chemical. And it is the act of suspension and ultimate cancellation that triggers this responsibility on the part of the Government to indemnify costs or to pay for disposal.

Senator MELCHER. Well, if I am not mistaken, I believe there have been some cancellations of hydrocarbons, chlorinated hydrocarbons, since FIFRA was enacted in 1972. In each of those cases, was a finding of imminent hazard by EPA made?

Dr. MOORE. No.

Senator MELCHER. It was not. What is the difference?

Dr. MOORE. The basic difference is that under a straight proposal to cancel, the Agency is basically reaching a conclusion that, indeed, the continued use of that registered material poses an unreasonable risk after having conducted a risk benefit finding.

Under suspension, we are saying that there is an imminent hazard in addition to having made the unreasonableness finding.

Senator **Melcher**. So in the case of several chlorinated hydrocarbons, they were suspended, removed from the market, but gradually; is that true?

Dr. **Moore**. Right. Actually you have the term wrong. For chlordane and DDT, for example, they were canceled. They were not suspended before they were canceled.

Senator **Melcher**. All right. They were canceled.

Dr. **Moore**. Yes.

Senator **Melcher**. But they were removed from the marketplace gradually; is that it?

Dr. **Moore**. Yes, in both instances. I believe it was after a hearing was held that the proposed cancellation was then reaffirmed, and then the licenses, if you will, for continued use were gone. In those instances, there was an existing stocks provision where the stocks were basically allowed to be used up as opposed to suspension action where the stocks are essentially stopped dead in their tracks, not permitting any future use.

Senator **Melcher**. Well, I was one of those who in the 1960's experienced the situation where stocks that we had were phased out, that is they were gotten rid of, but nothing was available to replace them of the same formula. Those are the chlorinated hydrocarbon that was found to be injurious to health. Is not the finding of an imminent hazard and everything that triggers a better public health measure or system to follow than just phasing out something that is already distributed, thereby leaving thousands of different users and allowing the product to be used over the next 2 or 3 or 4 or 5 years before it is removed?

Dr. **Moore**. Senator, I think in the use patterns of some chemicals one can make a determination that we as a country do not want to continue to allow those to be used in the future because if we have preferable alternatives that maybe pose less risk.

On the other hand, using the most recent suspension that the Agency invoked last fall, dinoseb, the feeling there was that the risk of birth defects to women of childbearing age was of such a health significance that one needed to get this material off the market while the cancellation process had a chance to work its will to see if, indeed, that was going to be a final outcome. In that dinoseb instance, we felt that the risk was so immediate and real that, indeed, it should go off the market rather than go through the more traditional pace of cancellation and maybe letting the market purge itself of residues of use.

Senator **Melcher**. Well, the public and the market are both built up of consumers who prefer to use what they know works rather than purchase something to replace a product they already have and know is effective even though quote, your "preferable"—I think you used the term "preferable product," is less harmful; is that right?

And so my question is simply this: When you use this term "imminent hazard," that refers to an immediate action, immediate suspension; right?

Dr. **Moore**. Yes, sir.

Senator **Melcher**. Not necessarily a cancellation?

Dr. **Moore**. No, it's an immediate suspension.

Senator **Melcher**. Immediate suspension. From a public health standpoint is that not a more effective tool to use?

Dr. **Moore**. Well, it is rather dramatic, and it is very tangible, and that exposure theoretically from that moment stops.

Senator **Melcher**. For instance, there is no hearing process prior to declaring an imminent hazard and suspending the use of a product; is there?

Dr. **Moore**. There is an opportunity in the statute for somebody to go to a Federal court in a very limited period of time to contest the suspension.

Senator **Melcher**. Yes, but there is no hearing process that EPA holds; is there?

Dr. **Moore**. No. The basic difference between suspension and cancellation is that when you suspend a chemical, you are also proposing to cancel it in the long term, but that, indeed, during the cancellation hearing, if one is to be held, the chemical cannot be used during the pendency of that hearing if you have suspended it.

If you have not suspended it, the chemical can continue to be used while the cancellation process works its will.

Senator **Melcher**. Well, I was one of those in 1972 that voted for FIFRA and went through the process of determining what ought to be in that statute. It is my recollection, though I admit it is very fuzzy, that we instructed in the statute that EPA was to use this imminent hazard procedure to move effectively and efficiently to suspend the use of some product that was a question of public health that also triggered the indemnification process.

The other means that you had, for instance, suspending some chlorinated hydrocarbons which had been long on the market—as long as 25 years, I believe, at that time—was a different process and that would be a gradual process. But the other process while using its authority for "declaring an imminent hazard," immediate suspension, that was different and triggered the indemnification process. I have been trying to put this together in my mind over the past hour on just why we have an indemnification process in this instance where we do not have it with pharmaceuticals.

Do you know whether there is an exact parallel? I do not believe there is an exact parallel in EPA's use of imminent hazard in the case of pesticides and that used pharmaceuticals; is there?

Dr. **Moore**. I believe, in my limited knowledge, of the Federal Food, Drug and Cosmetic Act as it might relate to drugs, if the Commissioner of FDA felt that, indeed, there was an imminent hazard based on some finding on the drug, he could force an immediate recall.

Senator **Melcher**. Has he?

Dr. **Moore**. I do not know if he has forced, or whether or not there has been voluntary withdrawal of materials. Sometimes the lines blur.

Senator **Melcher**. All right. At least your testimony is very direct, repeal section 15. We do not have to probe you on what the solution is. We have your recommendation.

Dr. **Moore**. Simple declarative sentence.

Senator **Melcher**. That is easy to understand. Thank you, doctor.

The **Chairman**. Thank you, doctor. Senator Wilson.

Senator **Wilson**. I think he has been quite clear.

The **Chairman**. Senator Fowler.

Senator **Fowler**. Dr. Moore, I want to continue the effort at clarity and directness. What is your position on S. 1419, the Ground Water Safety Act of 1987?

Dr. **Moore**. We certainly have not studied that in the detail that we have studied the main FIFRA bill. The ground water bill, again, in contrast to the bills or the language that were in the FIFRA bills of last year we think, has shown great improvement, particularly in acknowledging the need for a preventive approach rather than a reactive approach, for example, a highly contaminated well.

There still may be some difficulty in the setting of this reference point as far as the language proposed to amend the Safe Drinking Water Act and the setting of this natural contaminant level.

Senator **Fowler**. I am sure we would like to get your suggestions on any of the matters contained within the bill so that we can move forward. I would appreciate that in writing, if possible. I am sure the chairman would keep the record open for that response.

[The information requested by Senator Fowler can be found on pages 51 and 52.]

Senator **Fowler**. That is enough for right now.

The **Chairman**. Doctor, I wonder if you could tell me your feelings about the role of the States in S. 1419?

Dr. **Moore**. Senator, our feeling is that when we identify a chemical that has the potential to leach, we can clearly identify the factors that we think enhances its ability to leach to ground water. It is then possible to take that information and combine it with use patterns that are going to vary quite differently across this country. However, to make a decision as to how to best fine tune whether or not this chemical can be used, and if so, when it can be used, is probably a level of detail and complexity that just cannot be done at a national level.

So we think that the decisionmaking has to get closer to the field where the chemical is going to be used which, I think, translates into having to have a State role in trying to manage that type of a process. Failure to manage that type of a process, I think, dooms us to ending up with instances of contamination of ground water that none of us want to happen.

The **Chairman**. One of the associations that will testify here today has proposed an amendment to FIFRA that would require EPA and the States to coordinate and synchronize data requests. Now, I would like to know what your opinion is of that proposal. There are several questions that come to mind. Let me ask you the questions to help you give your answer by giving you an idea of what I am looking for. How would you interpret concurrent and identical? Could passage of that amendment preclude the States from asking for additional test data, or wait until EPA asks for the data? How long might a State or Agency have to wait?

Dr. **Moore**. Well, I think what is likely to happen is it would end up being somewhat of a Federal preemption of a State's ability to ask for such data. I believe the thrust of the bill conceptually has merit. Basically, one wants to ensure that some slight nuance of test procedure does not require a study to be duplicated that is essentially the same if it is conducted for State *x* or for the EPA.

I think the problem that really comes into play and which leads us to suggest that we do not favor the bill, is the logistics of working it out in a way that does not seem to be too heavyhanded on the part of the Federal agencies to the States.

The CHAIRMAN. How do you feel about giving citizens the right to sue the Administrator to enforce the deadlines in the bill? How do you feel about an amendment concerning citizen suits?

Dr. MOORE. If the citizen suit is focusing essentially on the ability of the Agency to do that which the statute directs it to do or its failure to do what the statute directs it to, there would be great objection on the part of the Agency, assuming it had a common provision for a 60-day notice before one can file and things of that sort.

The CHAIRMAN. S. 1516 has a lot of different deadlines for the completion of various tasks, both to protect the public health and the environment. I am wondering whether EPA would object to an inclusion of a provision for citizen suits designed to enforce those deadlines?

Dr. MOORE. If you get to the stage where the statute was going to pass that had the deadlines in it, and if there was the wherewithal within the statute that we thought we had the ability to meet those deadlines, I would probably answer it saying that we would not object.

We obviously would object if, indeed, we thought that the requirements in the statute and our ability to meet them guaranteed us to be put under court orders.

The CHAIRMAN. You do not want us to write a statute that looks great but has no money in it?

Dr. MOORE. Correct.

The CHAIRMAN. I am going to have to leave for another hearing. Senator Fowler of Georgia has been kind enough to offer to take over at this point, but you do not have to leave yet, Pete. We were just getting to the California panel now. Do you have any other questions for Dr. Moore? Dr. Moore, I appreciate your being here again. We may have further questions. I want to compliment you and your staff one more time on your efforts in working with us.

I know we have had a lot of questions for you and your staff, and I appreciate the cooperation.

Dr. MOORE. Thank you.

The CHAIRMAN. I am going to call up Janet Hathaway, senior project attorney for the Natural Resources Defense Council; Maureen Hinkle, the Director of Agricultural Policy for the National Audubon Society; and Margaret Seminario, the Associate Director, Department of Occupational Safety, Health and Social Security of the AFL-CIO.

I should note that the chairman's leaving is not a reflection on the testimony of this panel. These are all people with whom I have worked, and my office has worked; people for whom I have a great deal of respect, and I apologize for having to step out.

STATEMENT OF JANET S. HATHAWAY, SENIOR PROJECT ATTORNEY, ACCOMPANIED BY AL MEYERHOFF, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, WASHINGTON, DC

Ms. HATHAWAY. Thank you, Mr. Chairman. My name is Janet Hathaway, and I am senior project attorney with the Natural Resources Defense Council. We appreciate this opportunity to testify before the committee on S. 1516. Accompanying me is Al Meyerhoff, NRDC senior attorney.

NRDC commends Chairman Leahy and Senator Lugar for introducing S. 1516. The bill, which in many respects parallels the House-passed bill of October 16, 1986, is a substantial step toward an effective Federal pesticide law. S. 1516 sets a strict schedule for comprehensive testing and reevaluation of pesticides through the reregistration process.

It creates a program for assessing so-called "inert" pesticide ingredients, improves EPA's authority to make changes in pesticide labeling, establishes penalties for the submission of invalid health or safety data, and increases opportunities for public scrutiny of these data. All of these provisions in S. 1516 would improve EPA's authority to protect public health from pesticides.

I would like to focus my remarks on three possible amendments to S. 1516: One proposal, a preemption amendment, which we hope the committee would reject; and two proposals, registrant disposal of banned pesticides and citizen suits, which we urge the committee to adopt.

We are pleased that S. 1516 includes neither the liability amendment nor the tolerance preemption amendments of last year, which we believe were partially responsible for the demise of last year's legislative efforts. However, a new preemption effort is underway.

Proponents of the State registration preemption amendment maintain that it is designed to avoid redundant and inconsistent data demands on pesticide registrants. We do not believe that would be the effect. In fact, the amendment would effectively prevent States from carrying out testing programs. EPA would be required to set a schedule for data development which would preempt all State or Federal pesticide data requirements or timetables.

The State/Federal partnership which now exists has not proven unworkable. The consequence of this proposal would be bitter administrative and legal battles between the States and EPA during the pendency of which no one would be sure which State pesticide regulations, if any, were valid and enforceable. Chaos in State pesticide programs would ensue. We urge the committee to reject this preemption effort.

NRDC supports S. 1516 strengthening of EPA's authority to learn where banned pesticides are stored and in what form and quantity. However, the Government disposal obligation is both technically problematic and immensely costly.

EPA estimates that storage and disposal of the suspended herbicide dinoseb may cost over $100 million. Contrast this $100 million with the meager annual budget of the Office of Pesticide Programs, $40 million.

Pesticide containers are not ordinarily designed for long-term storage. Although some uses of EDB were first suspended in 1983, EDB stocks until this year were being stored awaiting disposal in the very containers in which they were sold. These containers were not designed to withstand corrosive effects of this chemical.

EPA believes that approximately 20 to 30 percent of all EDB stocks stored in Liberty, MO—amounting to thousands of gallons—leaked from their corroded containers into the environment. Dinoseb is an even more corrosive substance than EDB and may pose even more severe storage and disposal problems.

EPA greatly needs a recall authority to ensure that registrants have the obligation to safely store and dispose of suspended or canceled pesticides.

Let us turn briefly to a proposed citizen suit in FIFRA. NRDC believes that citizen suits enhance scarce Government enforcement resources. We urge the committee to amend S. 1516 to enable citizens to ensure that EPA carries out the requirements of the pesticide law.

All other statutory citizen suits are broader than the provision NRDC is seeking here. The other statutes enable citizens to sue any person violating any provision of the law. Studies have not shown abuse of the citizen suits now in 12 other environmental laws.

However, some have objected to a citizen suit in FIFRA because of fears that farmers would be sued. NRDC supports a narrow citizen suit provision to ensure that only the Government could be sued and only if it violates mandatory duties under the law.

I would like to explain what NRDC's proposal would not do. First, the citizen suit would not enable anyone to sue for money damages. Court orders or injunctions would be the only available remedy. Second, the provision would not result in suits against farmers or registrants. Only suits against the Government for failure to carry out congressionally established mandates would be allowed.

Third, frivolous or harassing litigation would not be allowed. There are already sufficient disincentives to bringing all but the most meritorious citizen suits.

Unless citizens themselves can ensure that the Government will comply with the law, the distrust that many people harbor for EPA's pesticide program will only deepen.

NRDC supports S. 1516's indemnification limitations and fee enhancements, and we will work with you to improve the law and to ensure its passage in this Congress. Thank you.

[The prepared statement of Ms. Hathaway follows:]

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TESTIMONY
OF
JANET S. HATHAWAY
ON BEHALF OF THE
NATURAL RESOURCES DEFENSE COUNCIL

CONCERNING REAUTHORIZATION OF
THE FEDERAL INSECTICIDE, FUNGICIDE, AND
RODENTICIDE ACT (FIFRA)

AND S. 1516

BEFORE THE

COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY

United States SENATE

JULY 30, 1987

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Thank you for the opportunity to testify before the Agriculture Committee on S. 1516, the Federal Insecticide, Fungicide and Rodenticide Act Reform of 1987. My name is Janet Hathaway, and I am Senior Project Attorney with the Natural Resources Defense Council (NRDC). Accompanying me is Al Meyerhoff, NRDC Senior Attorney. NRDC is a nonprofit membership organization dedicated to public health and environmental protection through scientific research and legal advocacy.

NRDC has frequently appeared before this Committee to urge reform of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In earlier testimony before this and other committees, we have documented the failure of the current law to adequately protect citizens--both as workers and as consumers--from exposure to pesticides.

FIFRA HAS NOT PROTECTED THE PUBLIC FROM PESTICIDE RESIDUES IN FOOD.

As NRDC testified before this Committee in May, we believe that the FIFRA has not adequately protected the public from pesticide residues in foods. The magnitude of the potential risk from cancer-causing pesticides in use on food was recently illustrated by the National Academy of Sciences in their report, Regulating Pesticides in Food: The Delaney Paradox. Estimates of cumulative risk from only 28 pesticides used on food amounted to nearly 6 cases of cancer in a thousand persons exposed over a lifetime (i.e. 5.84×10^{-3} excess cancers).[1] Considering the population of the United States, lifetime risks from this preventable cause of cancer could amount to 1.46 million cancers in the United States alone.

Although the NAS maintains that these estimates are based on some conservative assumptions, the report may in fact understate risk for several reasons. First, although the NAS report assumed residues at the legal limit or "tolerance" level, the General Accounting Office (GAO) has found that pesticides occur at greater than tolerance levels in 2 to 4 percent of foods.[2]

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[1] National Academy of Sciences, Regulating Pesticides in Food: The Delaney Paradox, Table 3-10, page 69, 1987.

[2] General Accounting Office: "Pesticides: Need to Enhance FDA's Ability to Protect the Public from Illegal Residues," October 1986, page 18.

Therefore, some people may experience higher exposures than those estimated by NAS.

Second, the report investigated dietary risk associated with only 28 cancer-causing pesticides. Because hundreds of additional pesticides are used on foods, many of which have never been adequately tested for carcinogenic potential, the NAS figures may understate risk. At least 27 additional pesticides have been identified by EPA as capable of inducing cancer.[3] For example, daminozide, a pesticide used primarily on apples as a plant growth regulator is estimated to have the potential to cause 8.3×10^{-3} additional cancer cases.[4] The risk from daminozide was not included in NAS's cumulative estimate of dietary risk, because NAS only considered dietary risk from herbicides, insecticides or fungicides identified as carcinogenic by EPA. However, the risk from daminozide alone exceeds the combined risk from the 28 carcinogenic pesticides examined by NAS.

Third, NAS may understate the risks from pesticides in our foods because it considered only active ingredients. Other substances found in pesticides include "inert" ingredients, metabolites and contaminants. Inerts are substances which are used to dilute or transport the active ingredient, but which are not intended to affect the target pests. Despite their misleading name, "inerts" may be toxic to humans. Earlier this year, EPA issued a Federal Register notice listing 57 inerts of toxicological concern.[5] At least fifteen of these chemicals-- including benzene, carbon tetrachloride, chloroform and formaldehyde--are carcinogenic substances.

Fourth, the NAS report did not consider the contribution to dietary risk from pesticide-contaminated drinking water. Both surface and ground water used as drinking water have been found to be contaminated with pesticides, including the carcinogen alachlor. Therefore, NAS's failure to consider this route of dietary exposure to pesticides may result in an unduly low estimate of risk.

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[3] National Academy of Sciences, op. cit., pages 4 and 47.

[4] National Academy of Sciences, op. cit., Table 3-30, page 89.

[5] Federal Register, April 22, 1987, Vol 52, No. 77, page 13306.

Fifth, NAS study may understate the risk because it did not consider potential synergism between various pesticide exposures. Exposure to some combinations of chemicals may result in a carcinogenic potential greater than the additive effect of the separate chemical exposures.

Sixth, NAS cumulative dietary risk estimates were based on average food consumption data. Many individuals and various subgroups of the population will eat more of the relevant foods and therefore experience greater exposures than the report estimates. The NAS report acknowledges the fact that "roughly 45 percent of the population will be consuming higher levels" of food than estimated in the study.[6]

Many pesticide manufacturers and food producers have responded to the NAS report by asserting that the NAS calculations exaggerate risk by assuming pesticide residues at the tolerance level. Actual residue data for most pesticides used on food is unavailable, incomplete or of questionable validity. However, even if one assumes adequacy of actual residue data provided by registrants to EPA concerning two fungicides, benomyl and mancozeb, the level of risk posed is significant. EPA estimated total dietary cancer risk from mancozeb based on average field residues at 2.2×10^{-5}. EPA estimated the cancer risk from benomyl at 7.2×10^{-6}; also based on average residues and the percent of crop treated.[7] For the current U.S. population over a lifetime of exposure, the risk based on actual residue data from just these two pesticides would be expected to result in approximately 7,000 additional cancer cases.

EFFORTS TO REFORM FIFRA IN THE 99TH CONGRESS.

Prospects for successful FIFRA reform never appeared brighter than last Congress when representatives of environmental, consumer and labor organizations engaged in exhaustive negotiations with representatives of the National Agricultural Chemicals Association (NACA) and the American Farm Bureau Federation. The long-awaited product of many months of negotiation was hailed by the press and the public for breaking the FIFRA deadlock. For a time it appeared that the compromise we reached could become law. Unfortunately, our fragile agreement had a very short life.

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[6] National Academy of Sciences, Regulating Pesticides in Food: The Delaney Paradox, 1987, page 192.

[7] See Environmental Protection Agency, "Guidance for Reregistration of Pesticide Products Containing Mancozeb," April 1987, page 23; and Memorandum from William Burnam, Deputy Chief, Toxicity Branch, U.S. EPA to Mr. Jeff Kempter, Chief, Special Pesticide Review Division, U.S. EPA, Regarding Benomyl Risk Assessment, May 18, 1982.

Despite promises to oppose all amendments, certain parties to the negotiations advocated two amendments vehemently opposed by the environmental, labor and public interest community. Over our objections, these amendments were included in a bill passed by the House on October 16, 1986. We believe that these amendments were among the chief reasons that the Senate refused to adopt the House-passed bill in the last days of the session.*

Among the amendments which violated and destroyed the negotiated compromise between public interest and industry were proposals to limit liability for farmers and an amendment to undermine state power to regulate pesticide residues in foods. Additional amendments inserted in the House bill of October 16th which were outside of the scope of the agreed-upon package included an amendment which weakened EPA's authority to collect fees to fund the reregistration program and an amendment which undermined the Senate-passed ground water protection provisions. For these reasons, the October 16th bill was unacceptable to NRDC, despite the many improvements to the current law which it embodied. NRDC did not attempt to kill the October 16th bill, but instead worked feverishly, albeit futilely, to eliminate the offensive provisions in the waning days of the 99th Congress.

ATTEMPTS TO REVIVE FIFRA LEGISLATION IN THE 100TH CONGRESS.

NRDC commends Chairman Patrick Leahy and Senator Richard Lugar for introducing S. 1516. The bill, which in many respects parallels the House-passed bill of October 16, 1986, is a substantial step toward an effective federal pesticide law. A laudable feature of the Leahy-Lugar bill, S. 1516, would establish a mandatory timetable for the call-in of missing data needed for reregistration of all currently-marketed pesticides and then set a brief period for E.P.A. to re-evaluate the safety of the pesticides. The bill also establishes a program for evaluating so-called "inert" pesticide ingredients, improves EPA's authority to make changes in pesticide labelling, establishes penalties for the submission of invalid health or safety data, and increases opportunities for public access to pesticide health and safety data. All of these provisions in S. 1516 would improve EPA's authority to protect public health from pesticides.

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* See James Aidala, Congressional Research Service, "What 'Killed' FIFRA?," October 31, 1986 and "Pesticide Regulation: Legislative Debate About FIFRA in 1986," May 11, 1987.

However, NRDC believes that a few amendments which would vastly improve the bill should be carefully considered. Among the strengthening amendments we seek are an effective ground water protection provision, citizen suits to ensure that the government carries out the mandates of the law, export controls, worker protection and right-to-know, EPA authority to order recalls of imminently hazardous pesticides, and improved pesticide disposal provisions.

NRDC anticipates a number of amendments may be offered which would greatly weaken S. 1516. Among the amendments we will strongly oppose are a provision to modify farmers' liability, an amendment to preempt state authority to set tolerances limiting pesticide residues in foods, and an amendment to severely undermine state pesticide testing and registration programs by mandating "identical and concurrent data requirements by all [federal and state] agencies."[9] I will first explain in detail our concerns about these three weakening amendments and then describe the strengthening amendments we support.

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[9] H.R. 2869, an amendment to FIFRA introduced in the House of Representatives on July 1, 1987 by Representatives Steve Gunderson (R-WI) and Pat Roberts (R-KS).

PREEMPTION OF STATE AUTHORITY TO SET TOLERANCES FOR PESTICIDES RESIDUES IN FOODS.

Last year the Senate Agriculture Committee approved an amendment which would effectively preempt state authority to set more stringent tolerances for pesticide residues in foods than those set by the federal government. The entire environmental, labor, and public interest community adamantly opposed the amendment. NACA also opposed the amendment. The preemption amendment was ultimately deleted from the bill on the Senate floor following a lengthy floor debate.[10]

Last year's Senate Agriculture Committee bill, S. 2792, at section 801(d) a provision requiring uniform tolerances set at the federal pesticide residue level for all pesticides registered or reregistered after April 25, 1985. Although the provision enabled a state to petition the Administrator to allow the state to set a different tolerance, the state's authority to use such a divergent tolerance is limited in several ways.

First, state petitions for more stringent tolerances would be granted only if the requirement is 1) justified by "compelling local conditions," 2) "will not unduly burden interstate commerce," and 3) will not cause food to be in violation of federal law. Thus, if a state disagreed with EPA's evaluation of scientific data or assesses the risks and benefits of the pesticide differently than EPA but can provide no evidence of local conditions which are compelling, the state could not establish a more protective tolerance for its citizens. And even where a "compelling local need" could be shown, EPA might still reject the petition if it found that the divergent tolerance would unduly burden interstate commerce.

Second, even if the state were able to establish a more stringent tolerance under section 801(d), the state would be prohibited from enforcing it under many circumstances. According to section 801(d)(1)(B)(i), if at the time of pesticide application the sale of the treated produce was legal, the state could not subsequently enforce against the tainted foods even if they exceed the state residue limits. This so-called "pipeline" proviso effectively eviscerates state enforcement of more stringent tolerances. In order to prove violation of a state tolerance, in addition to establishing excessive residues of the pesticide the state would have to demonstrate when and where the commodity was treated. Seldom would a state have such information necessary to the enforcement of its more stringent tolerances.

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[10] Congressional Record, S15312-S15332, October 6, 1986.

Finally, all more stringent tolerances set by a state would be subject to lawsuits. In a lawsuit challenging the more stringent state tolerance, the normal burden of proof would be reversed. Instead of requiring the petitioner to demonstrate that the governmental action was improper, the provision requires, "The state shall bear the burden of proof in any such action.[11] So even if a state, reduced from a sovereign to a supplicant before EPA, nevertheless is a successful supplicant, the state would still bear the burden of proving the appropriateness of the standards in any subsequent court challenge by a disgruntled farmer, food processor or neighboring state.

The state's current authority to set tolerances would not simply be narrowed by such a provision. The state authority that emerges from all of these constraints differs little in practical effect from no authority at all. The provision concerning uniform tolerances in last year's Senate bill is tantamount to preemption of the state authority to set pesticide tolerances.

NACA representatives recently testified before the House Agriculture Committee that they believe such an amendment concerning tolerance-setting authority to be "desirable."[12] NRDC strongly disagrees. The environmental, labor and public interest community continues to be united in its opposition to any such amendment.

Proponents of the tolerance preemption amendment say that it is needed to prevent a "crazy quilt" of conflicting legal requirements which would complicate or interrupt interstate commerce of agricultural produce. Unfortunately, this assertion lacks an empirical foundation. Experience has revealed that states exercise their authority to set more stringent pesticide tolerances cautiously and only in compelling circumstances.

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[11] S. 2792, 99th Congress, section 801(d)(4).

[12] Testimony of Dr. Jack Early, National Agricultural Chemicals Association, before the Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives, June 10, 1987.

States have acted to set more stringent tolerances only when faced with extreme inertia in the federal regulatory effort together with ample evidence that public health was not adequately protected by federal tolerances. There are hundreds of pesticides approved for uses on food. Two pesticides have been the subject of state efforts to tighten federal tolerances: ethylene dibromide (EDB) and daminozide.

In both instances, many years of ineffectual federal efforts preceded state action to tighten the tolerances beyond the levels set by the federal government. In both instances, compelling evidence was available on the basis of which state health authorities concluded that the risks from these pesticides were great, particularly for children. Finally, there is good reason to believe that the states would have preferred swift and decisive action by the federal government to the exercise of state authority. Contrary to the proponents' characterization of the EDB and daminozide incidents as stemming from a surplus of conflicting and overlapping authorities to set tolerances, these events demonstrate the confusion and danger which result from the federal government's failure to exercise its authority to revise tolerances when new data reveal risk.

A. ETHYLENE DIBROMIDE

Ethylene dibromide was first registered for food uses in 1948. EDB was used as a soil fumigant to kill nematodes as well as a post-harvest fumigant for grains and citrus. In 1956, on the basis of assumptions that no residues would remain on foods, EDB received an exemption from tolerance. The National Cancer Institute identified EDB as carcinogenic in 1974. In the late seventies, evidence established that contrary to expectations residues of EDB persist in food. EPA also obtained information confirming EDB's acute toxicity and adverse reproductive effects. Nevertheless, EPA's 1980 preliminary decision to cancel use of EDB was halted after Reagan Administration officials met with representatives of the food industry.[13]

In 1983 EPA took the first of a series of steps to limit use of EDB. EDB's use as a soil fumigant was suspended in September of 1983.[14] At the same time, EPA also began cancellation of the use of EDB as a grain and citrus fumigant, to become effective on September of the following year.[15] In February of 1984, uses of EDB on stored grain and grain milling equipment was suspended on an emergency basis.[16] Finally, in March of 1984, EPA announced a "phase out" over the next six months of EDB used to fumigate citrus.[17]

Despite these efforts to stop the domestic use of EDB, EPA still took no action to limit residues in food. Instead, Agency officials, including former Administrator Anne Gorsuch, convened numerous meetings with other Administration officials and representatives of food processing companies which are now spearheading this preemption effort in the Congress.[18] Although these food companies were able to persuade some Administration officials to delay action on EDB, they had less noteworthy success in certain states. NRDC believes that the drive to preempt the states was fueled by the frustration and surprise that certain food companies experienced when their influence in Washington, D.C. did not translate into power in the state capitals.

EPA calculated the dietary risk from EDB residues in grains as 3.3 cancer cases per 1,000 individuals exposed.[19] This calculation did not include risk from dietary exposure to EDB residues in citrus or to EDB in drinking water. Actual residue testing done by some private and state laboratories indicated significant residues in many common foods. States began to exert their authority to protect citizens from exposure to EDB. Eight states required that baby food products have no detectable residues of EDB.[20] Some states also established tolerances for EDB in other foods. Finally, in April 1984, EPA established tolerances for EDB in foods--but the federal limits were higher than those already set by some states.

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[13] See Problems Plague the Environmental Protection Agency's Pesticide Registration Activities, House Committee on Government Operations, U.S. House of Representatives, 98th Congress, 1984.

[14] See 48 Federal Register 46228, September 28, 1983.

[15] See 48 Federal Register 46234, September 28, 1983.

[16] See 49 Federal Register 4452, February 3, 1984.

[17] See 49 Federal Register 17144, March 2, 1984.

[18] See Problems Plague the Environmental Protection Agency's Pesticide Registration Activities, House Committee on Government Operations, U.S. House of Representatives, 98th Congress, 1984.

B. DAMINOZIDE AND UDMH (UNSYMMETRICAL DIMETHYLHYDRAZINE)

The Agency's experience with daminozide is not dissimilar to the EDB story. Daminozide is a pesticide which was registered for food uses in 1968. Daminozide is primarily used on apples, but it is also used on peanuts, tomatoes, peaches, cherries, nectarines and grapes. Apples treated with daminozide ripen more slowly and are less likely to drop before harvest, are denser and store better, and have an enhanced color. However, five separate studies, including one conducted by the National Cancer Institute in 1978, demonstrated the carcinogenicity of daminozide and its metabolite, unsymmetrical dimethylhydrazine (UDMH). Toxicologi- cal evidence suggested that UDMH may be an even more potent carcinogen that daminozide itself. New data also revealed that the transformation of daminozide into UDMH is accelerated by heating, as occurs during cooking or processing apples into applesauce and apple juice.

On the basis of the accumulating evidence of the carcinogenic potential of daminozide and UDMH, many states became very concerned about the danger posed to infants and children who consume processed apple products such as apple juice and applesauce at disproportionately high levels compared to adults. Children are also known to be even more vulnerable than adults to carcinogenic exposure because of their incompletely developed immune systems and the greater likelihood that they will live beyond the latency period necessary for the development of cancers. Children's more rapid rate of cell development may also make them more susceptible to carcinogens.

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[19] Environmental Protection Agency, Ethylene Dibromide: Position Document 4, September 1983, page 69.

[20] California, Connecticut, Florida, Maine, Massachusetts, Michigan, New York and Texas.

Although the first study demonstrating a cancer risk was performed in 1973, there was no hint of regulatory action on daminozide until seven years later. Then in 1980 EPA initiated a series of closed-door meetings with the sole manufacturer of daminozide, Uniroyal.[21] In September 1985, EPA proposed to stop any further food uses of daminozide. Uniroyal insisted that the carcinogenicity studies were flawed, although the flaws noted were ones which would normally understate the risk. However, Uniroyal never initiated its own carcinogenicity tests on their product.

The chief public health officials in the states of New York and Massachusetts wrote to EPA in 1985 to register their concern about the risk from daminozide, particularly for children. These health officials recommended restriction or cancellation of food uses of daminozide.[22] However, in January 1986, EPA reversed its position and continued existing uses of daminozide, pending further study.

EPA also proposed on April 16, 1986 to reduce the tolerance for daminozide-treated apples from 30ppm to 20ppm.[23] Massachusetts has taken measures to minimize exposure to daminozide.[34] Inordinate delays at the federal levels led other states, including Maine and New York, to consider regulatory action to protect public health from daminozide.[35]

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[21] In accordance with a settlement obtained with EPA by NRDC and the AFL-CIO, this practice of secret consultations with pesticide manufacturers has been discontinued. Settlement agreement in NRDC et al. v. Ruckelshaus, No. 83-1509, (D.D.C., September 20, 1984.)

[22] Letter of Dr. Bailus Walker, Commissioner, Department of Public Health, The Commonwealth of Massachusetts, to Mr. Steven Schatzow, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency, January 16, 1985; Letter of David Axelrod, M.D., Commissioner of Health, State of New York to Dr. John Moore, Assistant Administrator, Office of Pesticide Programs, U.S. Environmental Protection Agency, October 25, 1985.

[23] See 51 Federal Register 12889, April 16, 1986. The rule implementing the tolerance modification became effective on January 16, 1987. See 52 Federal Register 1909, January 16, 1987.

States have never used their authority to set distinct tolerances where the federal government has already set adequately protective limits for permissible pesticide residues on foods. State authority has been used judiciously and only after protracted delays at the federal level. State power to set tolerances must be preserved to enable states to protect their citizenry when the federal government cannot or will not respond to pesticide problems.

PREEMPTION OF STATE PESTICIDE TESTING PROGRAMS.

The Chemical Specialties Manufacturers Association (CSMA) has proposed an amendment which would effectively destroy the efforts of some states to require comprehensive testing and reevaluation of pesticides on a timetable swifter than that set by the Environmental Protection Agency. On July 1st the amendment was introduced as a bill, H.R. 2869, by Representatives Steve Gunderson (R-WI) and Pat Roberts (R-KS). NRDC urges the Senate Agriculture Committee to resist this amendment.

Advocates contend that the amendment, H.R. 2869, is designed to avoid redundant and inconsistent data demands on registrants of pesticides. In fact, the amendment would effectively prevent states from carrying out testing programs. The amendment requires the EPA Administrator to develop rules within one year in order to "result in identical and concurrent data requirement by all the [federal or state] agencies." EPA would be required to set a schedule for data development which would preempt all other state or federal pesticide data requirements or timetables.

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[34] Action Levels for Poisonous or Deleterious Substances in Food, Mass. Admin. Code Tit. 105, 515.000 (1986).

[35] State of Maine Department of Agriculture, Notice of Agency Rulemaking Proposal, Daminozide/UDMH: Acceptable Residue Levels in Heat Processed Foods, May 28, 1986. Testimony of Ms. Marilyn DuBois, Chief, Bureau of Pesticide Management, New York Department of Environmental Conservation, before the Department Operations, Research and Foreign Agriculture Subcommittee of Agriculture Committee, U.S. House of Representatives, June 10, 1987.

States have always had the authority to require data submissions from registrants in order to protect the health and safety of their citizens. The consequence of this bill would be bitter administrative and legal battles between states and the EPA, during the pendency of which no one would be sure which state pesticide regulations, if any, were valid and enforceable. Chaos in state programs regulating pesticides would ensue.

Efforts to preempt state authority under FIFRA have previously been attempted, but never before has the preemption effort appeared in the guise of "data coordination." State preemption was unsuccessfully sought by many trade associations including the National Agricultural Chemicals Association and CSMA in 1982. The preemption provision was stripped from the 1982 House FIFRA bill by an overwhelming majority after lengthy floor debate established that neither the Administration nor the states sought such radical transformation of the federal-state partnership concerning pesticide regulation.[26]

H.R. 2869 would abandon concepts of state sovereignty and instead reduce each state to a mere supplicant before EPA, lobbying in favor of data requirements and schedules which the state wishes to impose. If EPA disagrees with the state's plan, the state's only chance for redress consists of an appeal to EPA's own Scientific Advisory Panel. Only if EPA's Panel decides the dispute in the state's favor, against EPA's position, would be state be able to pursue their testing program. The states' traditional sovereignty in public health protection is destroyed by this seemingly innocuous amendment.

States should not be stripped of their traditional role as protector of their citizenry. As the Washington Post stated in an editorial opposing the preemption amendment published at the time of the floor debate in 1982, "The people of a state also have the right to insist on higher standards in matters that concern them."[27]

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[26] Congressional Record, H5655-H5669, August 11, 1982. The preemption amendment was deleted by a vote of 250 to 154.

LIABILITY EXEMPTIONS FROM ALL FEDERAL LAWS FOR AGRICULTURAL PRODUCERS.

The Senate Agriculture Committee's bill in the 99th Congress, S. 2792, included a liability exemption for agricultural producers. NRDC would strongly object if any such amendment were to be offered to S. 1516. We believe that FIFRA reform would be jeopardized by any attempt to by-pass the committees with jurisdiction over all federal statutes this provision would amend.

The liability provision, at section 821 of last year's Senate FIFRA reform bill, would modify any Federal statute imposing liability on agricultural producers for pesticide use. Neither the provision itself nor the committee report specified which statutes would be amended or why any change was deemed advisable. Proponents of this amendment have never provided evidence that federal environmental laws or other any other federal statutes pose an onerous or unfair burden for farmers. Indeed, a representative of the American Farm Bureau Federation, the major proponent of the liability provision, stated at a public meeting this spring that the only liability problems farmers have identified are a consequence of state, not federal, law.[28]

NRDC believes that the liability provision in last year's bill raises more questions than it answers. For example, the provision modifies farmers' liability for "damages caused by pesticide use," but leaves the crucial term "damages" undefined. This word alone may prompt years of expensive and unnecessary litigation. The liability provision states, "Proof that the agricultural producer used the pesticide in a manner consistent with label instructions shall create a rebuttable presumption that the agricultural producer did not act negligently." On the crucial issue of who must bear the burden of proving that use was consistent with labelling, the section is silent.

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[27] "Pesticides and Federalism," Washington Post editorial, July 22, 1982.

[28] Mark A. Maslyn, American Farm Bureau Federation, meeting of the Newspaper Farm Editors of America, April 27, 1987.

Casting confusion over the liability provisions of the major federal environmental statutes may have been no individual's intention, but surely it would be the consequence of such an amendment. NRDC believes that the best resolution to the liability controversy is to drop the entire provision.

INDEMNIFICATION REQUIREMENT UNDERMINES EPA'S PESTICIDE PROGRAM.

Now I would like to discuss briefly some elements of S. 1516 that are important improvements over last year's legislation. With some modest modifications, these provisions would be even more effective. Among the improved provisions are the sections concerning indemnification, enhanced EPA authority over the disposal of banned pesticides, and enhanced reregistration fees. NRDC recommends strengthening the disposal authorities and adding a narrow citizen suit to enable individuals to ensure that the government performs its Congressionally-mandated role under the federal pesticide law.

NRDC believes that EPA has convincingly demonstrated that the indemnification provision has resulted in an unjustifiable drain on scarce government funds. Furthermore, we believe the indemnification provision in current law unreasonably impedes the Agency's exercise of authority to suspend and cancel highly dangerous pesticides. NRDC supports section 1301 of S. 1516, which would significantly narrow EPA's current obligation to pay the holders of suspended and cancelled pesticides the value of the product. Section 1301 would prohibit the agency from paying registrants and others for products deemed too dangerous to use unless Congress passes a specific prior appropriation for indemnification of the particular product.

Although NRDC would prefer an outright repeal of the indemnification provision in section 15,[29] S. 1516 would effectively halt indemnification except where pesticide manufacturers could convince Congress that failing to compensate pesticide companies for suspended products would prove unjust. It is appropriate that the burden be placed on pesticide registrants in each case to demonstrate to Congress that agency action halting the use and sale of a pesticide should entitle those who made the dangerous pesticide to the full value of the excess stocks from taxpayer funds. Last year the full Senate approved a FIFRA reform bill which included the restriction on indemnification which is part of S. 1516. NRDC believes that without a similar provision, curtailing the use of even a few imminently hazardous pesticides will deplete program funds which are intended to assure that all marketed pesticides are fully tested and evaluated for hazards.

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[29] 7 U.S.C. section 136m.

EPA Assistant Administrator for Pesticides and Toxic Substances Dr. John A. Moore testified before the House Agriculture Committee's Subcommittee on Department Operations, Research and Foreign Agriculture on April 7th concerning the importance of abolishing the indemnification provision. Dr. Moore subsequently provided further elaboration of the indemnification and disposal problems in testimony before the House Government Operations Committee's Subcommittee on Environment, Energy and Natural Resources on July 9th. Dr. Moore testified at the Government Operations hearing in response to questions that the indemnification provision does not protect public health. "All [indemnification] does is pay those holding the pesticides, whether manufacturers or end users. . . . It is in no way connected with disposal and storage."[30]

At the request of a Senate Appropriations Subcommittee, EPA recently estimated the cost of indemnities for seven high-risk pesticides which may be subject to cancellation.[31] EPA estimated the cost to the Agency of a decision to suspend and cancel each of these products:

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[30] Testimony of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, U.S. Environmental Protection Agency, House Committee on Government Operations, Subcommittee on Environment, Energy and Natural Resources, July 9, 1987.

[31] See Pesticide and Toxic Chemical News, May 20, 1987, page 16.

PESTICIDE	INDEMNITY COST
alachlor	$161.5 million
benomyl	$ 4 million
chlordane	$ 53.2 million
daminozide	$ 7.9 million
dinoseb	$ 30 to 50 m[32]
linuron	$ 35.6 million
methyl bromide	$ 23 million
TOTAL INDEMNITY COSTS	$315.2 to $335.2 million

EPA's Office of Pesticide Program's annual budget of $40 million is dwarfed by the total costs of indemnification of just these seven pesticides. It is ludicrous to force EPA to balance the need to protect public health from a dangerous pesticide against the future funding of the Agency's pesticide program. Yet that is an inevitable consequence of the section 15[33] requirement that EPA reimburse registrants for the value of the pesticide products EPA deems too dangerous to be used.

THE FEDERAL GOVERNMENT SHOULD NOT BEAR RESPONSIBILITY FOR PESTICIDE DISPOSAL.

Similar to the indemnification problem is the problem posed by FIFRA's mandate in section 19[34] obliging the Administrator to accept for disposal, at government expense, pesticides the registration of which has been cancelled. These dangerous pesticides are expensive even to store and transport properly. EPA representative testified that over $1.7 million has been spent so far to store the cancelled fumigant ethylene dibromide (EDB), and disposal of the pesticide has not yet begun.[35] Disposal is a technological problem for many of these pesticides, and the costs can be strikingly high. EPA estimates that the cost of disposal of the herbicide dinoseb will be at least as great as the $30-50 million estimate for indemnification.

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[32] Costs of dinoseb indemnification together with disposal could run as high as $100 million, according to EPA materials submitted to the Senate Appropriations Committee.

[33] 7 U.S.C. section 136m.

[34] 7 U.S.C. §136q.

Pesticide containers are not ordinarily designed for long-term storage. Although some uses of EDB were first suspended in 1983, EDB stocks are still being stored, awaiting disposal, in containers not designed to withstand the corrosive effects of this chemical. The disposal provision encourages lengthy storage of cancelled pesticides, without regard to the public health risks such storage may pose. EPA believes that approximately 20-30% of all EDB stocks stored in Liberty, Missouri--amounting to thousands of gallons--leaked from containers into the environment.[36]

All other manufacturers of hazardous substances bear responsibility for properly disposing of their products and wastes, regardless of whether the product is registered for use and sale in this country or whether the product is banned. The potential dangers from improper pesticide storage and disposal are great. Manufacturers are in the best position to promptly and safely detoxify or destroy excessive stocks of the products they made and sold at substantial profits.

NRDC supports the provision at section 508 of S. 1516 enhancing EPA's authority to identify where cancelled or suspended pesticides are stored and in what quantities. However, greater authority is needed. EPA should be given explicit statutory authority to require information on appropriate storage and disposal methods as a condition of registration. Furthermore, EPA should have the authority in appropriate cases to require a manufacturer to recall dangerous pesticide products at the manufacturer's expense. Just as recalls have served to protect citizens from defective automobiles or contaminated foods, a pesticide recall authority would improve the likelihood that banned pesticides are not simply dumped into empty lots or streams or abandoned in industrial warehouses. A manufacturer's recall would also protect farmers and other users who might otherwise indefinitely store or inadvertently use a product EPA had determined to be unreasonably dangerous.

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[35] Testimony of Dr. John A. Moore and other EPA witnesses in response to questions, before the House Government Operations Committee, June 9, 1987.

[36] Testimony of Dr. John A. Moore and other EPA witnesses in response to questions, before the House Government Operations Committee June 9, 1987.

ENHANCED REREGISTRATION FEES ARE ESSENTIAL TO EXPEDITE REREGISTRATION.

No program can succeed without adequate funding. Last year's Senate-passed bill would not have provided an adequate funding base for the acceleration of reregistration which is the heart of the bill. In 1986, EPA estimated the enormous revenue shortfalls at approximately $45-55 million, even before considering the effect of the exception for "small business registrants" at section 105(j)(4)(C).[37] It is exceedingly difficult for EPA to precisely estimate the extent of the shortfall because EPA is currently precluded from obtaining sales data on pesticides by section 8 of FIFRA.[38] Without detailed sales data, EPA cannot precisely calculate the revenue it would obtain from pesticide registrants which qualify as "small" businesses. This year EPA estimated that the total revenue shortfall which would occur if last year's bill had been enacted would amount to approximately $150 million over the life of the reregistration program.

NRDC is pleased that Chairman Leahy and Senator Lugar have succeeded in establishing reregistration fees which are believed to raise over $110 million the next five years. This improves the prospect of implementation greatly. However, we are concerned that the section 8 prohibition on financial and sales data may impede EPA in implementing the reregistration fees in S.1516, section 301(j). Furthermore, we are concerned that an unsympathetic Administration may fail to raise EPA's budget sufficiently to cover the $40 million anticipated shortfall. We would welcome increasing EPA funding to ensure that reregistration will occur according to the statutory timetables.

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[37] Senate Report 99-424, Report of the Committee on Agriculture, Nutrition and Forestry, United States Senate, to accompany S.2792, September 3, 1986, page 101.

[38] "No records required under this subsection shall extend to financial data, sales data. . . ." 7 U.S.C. 136f.

ENHANCE FIFRA ENFORCEMENT THROUGH A CITIZEN SUIT PROVISION.

NRDC believes that citizen suits are a valuable enhancement of scarce government enforcement resources. We urge the Committee to amend S. 1516 to enable citizens to ensure the Environmental Protection Agency and other agencies carry out the requirements of the pesticide law.

All other statutory citizen suit provisions are broader than the provision NRDC is seeking in FIFRA. The other statutes enable citizens to sue *any person* violating any provision of the law. Some have objected to a citizen suit provision as broad as those in other federal environmental laws because of fears that farmers would be subject to suits. Although we believe that a citizen suit provision parallel to those in other federal laws would not lead to inappropriate or harassing lawsuits, we would support a more limited provision to ensure that the *government* carries out all mandatory duties under FIFRA. Such a limited citizen enforcement provision is both essential and less controversial. NRDC believes that a narrow, but effective, FIFRA citizen suit provision would enable citizens to sue only *governmental agents* who violate the pesticide law.

Twelve federal environmental laws now contain provisions enabling citizens to enforce statutory requirements.[39] However, there currently is no right for citizens to sue to enforce provisions of Federal Insecticide Fungicide Rodenticide Act (FIFRA) and regulations promulgated under the Act. A citizen suit provision is crucial to ensure that violations of the Act or of regulations do not continue unabated.

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[39] Clean Air Act §304, 42 U.S.C. §7604; Federal Water Pollution Control Act, §505, 33 U.S.C. §1365; Toxic Substances Control Act, §20, 15 U.S.C. §2619; Resource Conservation Control and Recovery Act, §7002, 42 U.S.C. §6972; Noise Control Act, §12, 42 U.S.C. §4911; Safe Drinking Water Act, §1449, 42 U.S.C. §300j-8; Marine Protection Research and Sanctuaries Act, §105(g), 33 U.S.C. §1415(g); Endangered Species Act, §11(g), 16 U.S.C. §1540(g); Deepwater Port Act, §16, 33 U.S.C. §1329(a); Outer Continental Shelf Lands Act, 43 U.S.C. §1349(a); Surface Mining Control and Reclamation Act, §520, 30 U.S.C. §1270; Comprehensive Environmental Response, Compensation, and Liability Act of 1980 "Superfund"), as amended by the Superfund Amendments and Reauthorization Act of 1986, Pub. L. 99-499, section 206, 42 U.S.C. §9601 *et seq*.

Courts may derive a negative implication from the absence of a citizen suit provision in FIFRA and restrict the availability of private suits to enforce the requirements of the pesticide law.

In the absence of a FIFRA citizen suit, persons desiring to enforce the provisions of the statute would normally file a suit under the Administrative Procedures Act, 5 USC section 706, alleging that the Administrator's action (or inaction) is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Such a litigant must establish "standing" or an interest directly affected by the Administrator's action (or inaction). The successful litigant must also show that the affected interest was one which the pesticide law was designed to protect.

Courts do not automatically presume that public interest organizations have standing to enforce environmental statutes, even where the organization is well known for its commitment to enforcing such laws. Plaintiffs must show that members of the organization are directly at risk or in some other way significantly affected by the action. A court may also dismiss on standing grounds when it finds only a diffuse interest on the part of the public interest organization or an interest no different from that of every ordinary citizen. In the absence of a FIFRA statutory directive clearly announcing the intention of Congress to allow private parties to enforce the statute, the courts may assume that only exceptionally clear instances of direct interest constitute sufficient grounds for permitting private enforcement to proceed.

In the absence of an explicit statutory provision for a citizen suit, courts may also be less inclined to find Agency inaction unreasonable. One of the most important enhancements which the FIFRA reform legislation would provide is mandatory timetables for data call-ins, data submissions and reevaluation of old pesticides. In the absence of a clear Congressional directive enabling citizens to ensure that these schedules are met, courts may be reluctant to find that the Agency's failure to meet deadlines is "arbitrary, capricious. . . or otherwise not in accordance with law." In order to avoid any impediment to seeing the statutory mandates enforced, Congress should explicitly provide a citizen suit to enforce FIFRA.

Some argue that citizen suit provisions result in excessive and unjustified litigation. Evidence does not support this claim. The Environmental Law Institute (ELI) was commissioned by the U.S. Environmental Protection Agency[40] to study citizen enforcement actions under EPA-administered statutes. According to the analysis by ELI, cumulative actions under the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Toxic Substances Control Act and the Safe Drinking Water Act from 1978 through March 30, 1984 totalled 349. Of the 349 actions, 160 actions consisted only of notices. Only 189 cases involved the filing of lawsuits. The majority of actions were brought under the Clean Water Act (236 total; 113 notices and 123 suits filed). In over six years, the seven other environmental statutes accounted for only 113 actions, with 47 consisting only of notices and 66 lawsuits filed.[41] This hardly constitutes a flood of litigation.

One major deterrent to the bringing of citizen suits is, obviously, the expense. Environmental Law Institute reported, "Despite statutory authorization for recovery of attorneys' fees by victorious plaintiffs, citizen group representatives repeatedly noted the great difficulty they had in paying the 'up front' costs of these lawsuits."[42] ELI reported that the average litigation costs incurred by some two dozen individual plaintiffs bringing citizen suits was between $35,000 and $40,000. The lowest reported figure was about $4,000 and the highest was approximately $200,000.[43] These costs are obviously beyond the means of most individuals and many national organizations. The costliness is, unfortunately, likely to deter even the most meritorious cases.

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[40] EPA Contract no. 68-01-6558, Environmental Law Institute, Citizen Suits: An Analysis of Citizen Enforcement Actions Under EPA-Administered Statutes, September 1984.

[41] Environmental Law Institute, supra, page III-10.

[42] Id., page V-25.

[43] Environmental Law Institute, op. cit., pages V-25 and 26.

Another reason why the number of citizen suits have been fewer than anticipated is the difficulty, in many instances, of documenting statutory violations. Statutes establishing broad authorities but creating few mandatory duties, like FIFRA, are unlikely to spark numerous citizen suits. One of the reasons suggested for the fact that more than half of citizen suits actions were brought under the Clean Water Act is the ready availability of industry-submitted compliance data, which enables a potential plaintiff to easily identify violations. Such industry self-reporting occurs seldom with pesticide problems. Industry documentation of statutory violations is therefore not likely to be a common basis for FIFRA citizen suits.

Certain opponents of citizen suits have alleged that suits are frequently brought for trivial violations. Analysis by the Environmental Law Institute reveals no such problem.

> "None of the government enforcement personnel interviewed reported a general tendency for citizen groups to pursue trivial violations (a complaint frequently raised by industry spokesmen) . . . . Every government enforcement person interviewed acknowledged that some of the cases initiated by citizen enforcers had slipped through the state/federal enforcement net, and should have been the subject of government enforcement action. Most citizen suit cases, therefore, were acknowledged to be either 1) cases which EPA would have initiated in the normal course, or 2) cases which were 'enforcement worthy' but were not high on EPA's priority list."[44]

The ELI survey provides good reason to conclude that most citizen suits brought to date under the environmental laws have supplemented EPA's enforcement power and have focused on significant violations. Federal law already provides sufficient authority to penalize attorneys who bring trivial or harassing lawsuits. Sanctions, including costs of litigation and attorneys fees for the opposing party, can be imposed on any person who files a frivolous suit or who uses legal procedures to unnecessarily delay or increase costs.[45]

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[44] Environmental Law Institute, supra, pages V-9 and V-10.

[45] Federal Rules of Civil Procedure, Rule 11.

Other important findings by the Environmental Law Institute include the following:

- Only 48% of the citizen cases resulted in the filing of lawsuits. Nearly half of the cases were dropped because negotiations were initiated.[46]
- Of the citizen actions that resulted in the filing of lawsuits, 24% were settled before a judicial decision was made.[47]
- In 6% of citizen suits, the government intervened during the 60-day notice period and eventually filed suit, thereby precluding the citizen suit.[48]
- In 21% of citizen suits, actions were dropped because of a lack of resources, agency modifications of the regulations, weak evidence, compliance or settlement.[49]

Small numbers of citizen actions actually result in lawsuits, and nearly a quarter of these are settled prior to decision. These findings indicate that the burden of citizen suits on the federal courts is even less than the small numbers of notices filed might suggest.

Unless citizens can themselves ensure that the government will comply with statutory mandates, the distrust many citizens harbor for EPA's pesticide program will only deepen.

ENSURE GROUND WATER PROTECTION FROM PESTICIDES.

Although the bill as introduced does not include provisions to protect ground water from pesticide contamination, we expect that S. 1419, the ground water protection bill introduced by Senators Leahy, Durenberger, and others may be offered as an amendment to the FIFRA reform bill.

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[46] Id., page III-8, Figure B. "Reasons for Not Filing Suit Following Notice".

[47] Id., page III-4.

[48] Id., page III-4.

[49] Id., page III-4 and III-6.

Ground water protection is a vital but frequently neglected component of a sound pesticide regulatory program. Pesticides which are applied to crops may persist and migrate through the soil until they reach underground reservoirs or "aquifers." EPA reports that ground water contaminated with pesticides has been detected in 24 states, and a total of 20 pesticides have been identified.[80] These findings are startling because in rural areas, over 97% of drinking water comes from underground sources.[81] Nearly half of all Americans depend on ground water for drinking water and other essential purposes.

Recent detections of aldicarb in Long Island's ground water, which is the sole source of drinking water for 3 million people, led to use restrictions and ultimately to a ban on the use of the pesticide in Suffolk and Nassau counties.[82] In Florida, 828 wells tested positive for the nematocide ethylene dibromide (EDB).[83] California state agencies monitoring ground water discovered the nematocide dibromochloropropane (DBCP) in over 2,000 wells and identified over fifty different pesticides in the ground water of 23 California counties.[84]

There are many ways in which S. 1419 would greatly enhance federal protection of ground water from pesticides. First, EPA would evaluate each pesticide, at registration or reregistration, for its potential to leach into ground water. If the pesticide is a potential "leacher," EPA would be required to set limits for residues of the pesticide in ground water ("ground water residue guidance levels" or "GRGLs") and required to develop and disseminate management practices to minimize migration into ground water. Second, registrants of pesticides with a potential to leach will be required to monitor ground water in representative geographical and hydrogeologic areas and can be required to conduct additional monitoring, where needed.

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[80] U.S. Environmental Protection Agency, Agricultural Chemicals in Ground Water Strategic Plan, June 1987, p. I-11.

[81] Elizabeth G. Nielsen and Linda K. Lee, United States Department of Agriculture, The Magnitude and Costs of Groundwater Contamination from Agricultural Chemicals, June 1987, page 1.

[82] Patrick W. Holden, Pesticides and Groundwater Quality, Board on Agriculture, National Research Council, 1986, page 4.

[83] Holden, Pesticides and Groundwater Quality, op.cit., p.87.

[84] Holden, Pesticides and Groundwater Quality, op.cit., pp.15-16.

Third, registrants are required to inform EPA, the state, the property owners, and people relying on the ground water when pesticides are detected. Without such an obligation to notify when contamination is found, state and federal governmental programs will proceed oblivious to important evidence that a pesticide may threaten ground water.

Fourth, EPA must amend pesticide registrations to modify the conditions of use to protect ground water when detections occur above 25 percent of the GRGLs. Where the pesticide detections are even higher, at or above 50 percent of the GRGL, the federal government or the state is required to take action to prohibit local uses of the pesticide, to provide alternate water supplies for public health protection, or to require remedial treatment of the ground water. These provisions clarify and enhance EPA's ground water protection efforts. Even in the absence of explicit statutory changes, these powers are almost certainly within the Agency's current statutory authority under FIFRA, the Safe Drinking Water Act, and the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or "Superfund"). However, clear legislative directives, such as those provided in S. 1419, may defuse resistance and litigation which could otherwise delay a program to protect ground water from pesticide contamination.

NRDC anticipates that the appropriately broad definition of "underground source of drinking water" in S. 1419, which includes both current and potential sources of drinking water, will be under attack as the bill moves through the political process. Unless the bill provides broad protection not merely to aquifers now used or likely to be used in the near future, the new statutory authority will permit degradation of ground water resources which future generations might otherwise have used. No regulatory program can be truly protective of our nation's ground water unless it presumes that ground water which we currently consider undesirable may become a valuable resource in the future. Without such a presumption, a program which purports to protect ground water may in fact "write off" for contamination aquifers which future generations would otherwise have relied on for basic needs.

NRDC's greatest concern with S. 1419 is with section 1429, the section that sets forth the principles on which EPA should base the ground water residue guidance level (GRGL) for each leaching pesticide. Because most significant regulatory actions are triggered by detection of the pesticide at or near the GRGL, this standard-setting is the heart of the ground water program. A program which restricts the uses of leaching pesticides only when detections in ground water are confirmed is not, strictly speaking, a preventive program. However, if the GRGL is based on any considerations other than the protection of human health and the environment, the program is not even capable of ensuring that ground water will not endanger the public.

Unfortunately, S. 1419 allows GRGLs for carcinogenic pesticides to be based on the economics and technology of cleaning up water contaminated with the pesticide of concern. This is so because for pesticides with no threshold for chronic adverse effects (e.g., carcinogens), the GRGL may be set at a level equivalent to the maximum contaminant level (MCL) set under the Safe Drinking Water Act.[55] MCLs are based not solely on health effects but also take into account the costs of removing the contaminants from public drinking water supplies. Such a standard is out of place in a program which is designed to prevent contamination.

Section 1429(a)(2)(B)(ii) limits the use of MCLs for setting GRGLs to instances where "considering other exposure to the pesticide including dietary exposure, . . . concentrations of the pesticide in drinking water will not present more than a negligible risk of chronic adverse health effects. . . ."

NRDC does not believe that any preventable risk of chronic adverse effects such as cancer should be deemed a "negligible" risk. Furthermore, we believe that this statutory mandate will not be sufficient to constrain EPA from considering high risks, such as risks greater than one in a million of cancer, "negligible." Unfortunately, the vagueness inherent in such a phrase like "negligible risk" would most likely lead courts reviewing EPA's GRGLs to defer to the Agency claim concerning what is a negligible risk. Rather than improving the Agency's standard-setting, we fear that such a provision could insulate from strict scrutiny

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[55] S.1419, section 1429(a)(2)(B)(i).

EPA's use of standards incorporating inappropriate economic and technological considerations.

CONCLUSION

Reauthorization of FIFRA is a top legislative priority for NRDC. We are aware that the process is an arduous one, and we are committed to a constructive role throughout. NRDC appreciates the opportunity to discuss S. 1516 and S. 1419 with the Committee, and we will welcome all opportunities to assist in improving these important bills and ensuring the enactment of FIFRA reform legislation.

Senator **Fowler** [presiding]. Thank you, Ms. Hathaway. What is the remedy under the citizen suit proposal that you are——

Ms. **Hathaway**. If someone——

Senator **Fowler**. Just to stop them from doing it. You say there is no damages. You cannot sue the farmer. You are only suing the Administrator?

Ms. **Hathaway**. Yes. That is right. If you were successful in your citizen suit what you would get is a court order. If it were a schedule that you were concerned about that had not been adequately complied with by the Agency, what you would probably get is a court ordered schedule, a timetable, for carrying out the actions under the law. If instead you were complaining about a violation of a mandate, a failure for EPA to take into account some required criterion in establishing a regulation or something of that kind, you probably would get a court order telling EPA to go back and do their rulemaking once again, that sort of thing.

But you would not be getting money damages in any case.

Senator **Fowler**. Thank you very much. Next we have Ms. Maureen Hinkle, Director of Agricultural Policy for the National Audubon Society.

STATEMENT OF MAUREEN K. HINKLE, DIRECTOR, AGRICULTURAL POLICY, ACCOMPANIED BY DEBORAH MUNT, BIOTECHNOLOGY ASSOCIATE, NATIONAL AUDUBON SOCIETY, WASHINGTON, DC

Ms. **Hinkle**. Thank you, Mr. Fowler. With me today is Deborah Munt who will be pleased to answer any questions that you might have on the DNA section of our testimony. We appreciate this opportunity to testify and we particularly appreciate your improvements over the House bill. These improvements will provide more certainty for both EPA as well as the regulated community.

Because of the limited time remaining for consideration of legislation in this session, we will only bring up changes that we regard as essential.

In regard to the fees and resources that you have provided, although they seem to be between one-third and one-fifth short of what EPA needs in order to be fully appropriated, we believe if you struck indemnities and provided for disposal that these kinds of cost savings could compensate for the $30 to $40 million inadequacy. In regard to hearing rights by members of the public, S. 1516 tracks the House bill, and we appreciate the provision for any persons adversely affected by a final EPA decision to be able to request a hearing so that economic interest is not the sole determinant of who may request a hearing.

S. 1516 also requires that the person who requests the hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

In 1964, Congress placed on the registrant the ultimate burden of persuasion to show that his product meets the requirements of the law. This was upheld in 1972 when the U.S. Circuit Court stated, that "the burden of establishing the safety of a product requisite for compliance with the labeling requirements, remains at all times on the applicant and registrant." Again, in 1976, the U.S.

Circuit Court of Appeals said that "in its 1964 amendment to the act, Congress made clear that the public was not to bear the risk of uncertainty concerning the safety of a covered poison. In the absence of an equally explicit countermanding direction from Congress, we would not force the public to assume it."

The court pointed out that information relevant to safety issues are in the possession of the manufacturer. The registrant generates all of the data for submission to the Government; the Government is privy to all of the data—over a period of many years. To then place the burden of proof on the public after a substantial question of safety has been established is clearly unfair.

Therefore, the National Audubon Society respectfully requests you to retain the 23 years of existing law in which the Congress and the courts have stated that the ultimate burden of proof must be borne by the registrant. We hope that you will make sure that section 505 does not implicitly shift the ultimate burden of proof concerning the safety of the pesticides.

We agree with NRDC in requesting a citizen suit provision because FIFRA is now the only environmental statute that does not provide for a citizen suit action. The Toxic Substances Control Act, the Clean Water Act, the Safe Drinking Water Act, and the Clean Air Act all provide for citizen suits to be filed.

In regard to indemnities, in our prepared statement we support what you have in S. 1516. Our preference, however, would be what Congressman Synar and EPA Assistant Administrator Jack Moore ask for, which is having section 15 totally struck.

If that is not possible, we hope that the minimum of what you can do on indemnities is to hold to what you have in section 1301 of S. 1516. This would make indemnities payable to a company as a line item advance appropriation. This would allow a company to make a case that if it really truly deserved compensation out of taxpayers' funds they would get indemnities. But the public would at least know what it costs and would approve of it in advance.

We are glad that disposal has been brought up. It has been a hidden issue, out of sight out of mind, in a sense. When a registration is canceled, the registrant under current law can require EPA to assume the burden of disposal.

We would hope that you can include S. 1419, the Ground Water Safety Act of 1987 as a part of FIFRA. We oppose what the House has included on ground water, included as section 814 of H.R. 2463 and we do support S. 1419 for the reasons given in our prepared statement.

In regard to patent term extension, the Senate has incorporated patent term extension into S. 1516, which we believe to be unnecessary, given the automatic patent life that is provided in the data compensation sections.

We also believe that giving patent extensions to DNA products before this is addressed in the body of the legislation is premature Those are our comments in highlight. Thank you very much.

Senator **Fowler**. Thank you, Ms. Hinkle. Of course, all of your prepared statement will be made part of the record.

[The prepared statement of Ms. Hinkle follows:]

National Audubon Society

NATIONAL CAPITAL OFFICE 801 PENNSYLVANIA AVENUE, S.E. WASHINGTON, D.C. 20003 (202) 547-9009

STATEMENT

AT HEARINGS ON

S. 1516

TO AMEND

THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

BEFORE THE

SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

JULY 30, 1987

by

Maureen K. Hinkle
Director, Agricultural Policy
National Audubon Society

and

Deborah Munt
Biotechnology Associate
National Audubon Society

Mr. Chairman and members of this committee, my name is Maureen Kuwano Hinkle, and I am Director of Agricultural Policy for the National Audubon Society. National Audubon has been actively involved with FIFRA since the 1972 amendments were enacted, and has participated in major battles amending FIFRA in 1975 and 1978. I represented Audubon under a special grant given to the Environmental Defense Fund to watchdog the implementation of FIFRA mandates after the 1972 amendments were passed. In 1981 I moved from EDF to Audubon where I have continued this responsibility. In 1985 I was a party to a negotiated agreement on EPA's emergency exemption regulations promulgated in 1986. With me today is Deborah Munt, whose responsibility is bioengineered agricultural products.

The National Audubon Society appreciates this opportunity to testify on your proposed amendments to FIFRA, as well as your interest in moving a bill in this session of the 100th Congress. In particular, the National Audubon Society appreciates the improvements made on the core of negotiated agreements between the Coalition for Pesticide Reform and the National Agricultural Chemicals Association. Your improvements on the House version, H.R. 2463, appears to provide more certainty for both the regulator and the regulated than the House bill.

Because of the limited time remaining for consideration of legislation, Audubon will not bring up a number of changes we regard as essential. In the interests of moving the bill and providing much needed added resources to EPA, we limit our testimony today to the wording of the proposed bill, hearing rights, citizen suits, ground water and patent term extensions. We remain opposed to amendments that would prohibit states from acting more stringently than the federal EPA and granting liability waivers to farmers without placing responsibility for liability on the registrants or other responsible parties. We urge the committee to incorporate S. 1419, the Ground Water Safety Act cosponsored by members of this committee and the Environment and Public Works committee. Lastly, Audubon believes that the inclusion of patent term restoration for pesticides derived by recombinant DNA technology is premature. The patent term extension part was prepared by Deborah Munt, who will be pleased to answer questions you may have on that section.

FEES AND RESOURCES

S. 1516 has provided a schedule for reregistration fees to pay for additional resources needed to meet mandated deadlines. It is unclear to Audubon whether the structure the Senate has provided will be sufficient to pay for the additional mandates of these amendments.

Unless resources are assured, procedural deadlines for an "assembly line" list for checking off technical risks will again produce regulatory failure. Real and substantial risks will pass unexamined to meet tight time frames. If accelerated registration is virtually automatic, the public is clearly not protected. Hurried evaluation of the mass of data produced at such a cost by industry deserves efficient and fair review. Competent review assures sustained marketability of pesticides, since problems can be identified in advance and appropriate restrictions imposed to prevent "surprise" disasters, thereby protecting the public and industry alike. Reasonable deadlines are needed to force the agency to act more efficiently, but resources must be assured in advance before starting the clock on a set of specific deadlines.

S. 1516 places some of the burden of reformating data on registrants, and imposes a fee on new registrants which would decrease the burden currently handicapping the operation of the pesticide program. We are pleased that the Senate is seeking to impose a fee on all registrants in proportion to their actual revenue-generating potential and that such fees will be forwarded directly to the U.S. Treasury for use by the registration program.

REVIEW BY THE SCIENCE ADVISORY PANEL

Section 505 of S. 1516 provides a new subsection 6(f)(3)(F) which would submit "new studies not available during the public interim administrative review" to the Science Advisory Panel (SAP) for review and comment. Under the 1972 FIFRA, the administrative judge (hearing examiner) could refer "relevant questions of scientific fact involved in the public hearing" to the National Academy of Sciences. The 1972 FIFRA also specified that "No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee." (Section 6(d))

Before congress substitutes the SAP for a committee of the National Academy of Sciences to advise EPA on a study, all SAP members should be required to sign a financial or other conflict of interest statement. Even with such a statement, Audubon would like the alternative of scientific review by an Academy of Sciences committee if the SAP cannot be called in a timely schedule or does not have the expertise to review the new studies.

There may be studies or issues that are of such technical complexity that members of the SAP are not fully qualified to address. Although the SAP has, in the past, deputized scientists with such expertise, some issues deserve more than a one or partial day of review. The National Academy of Sciences could impanel several experts who essentially put their reputation on the line. The possibility of obtaining first rate scientific review by the Academy is much greater than a few hours by a scientist pulled into a SAP meeting. Whereas temporary panel scientists are fully competent technically, they seldom express views different from the SAP regulars.

HEARING RIGHTS

S. 1516 tracks the House bill, H.R. 2463, in regard to hearing rights by members of the public. We appreciate the provision for any persons adversely affected by a final EPA decision to be able to request a hearing, so that economic interest is not the sole determinant of who may request a hearing. We wish to emphasize, for those who may still question this right, that it is not an absolute right to request a hearing; it is limited in that EPA retains discretion as to whether or not to grant a hearing. Whereas a registrant has an absolute, i.e., automatic right to a hearing, an outside party requesting a hearing must make a prima facie case that a hearing is necessary. Such a requirement is necessary to prevent frivolous requests. The party requesting a hearing must prove they are adversely affected to obtain "standing to sue." EPA chooses the issue, which must be a substantial issue of fact. The deterrent is significant for to proceed with a hearing is a costly, resource-intensive undertaking.

S. 1516 also requires that "the person that requests a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue." (Section 505 -- inserting new subsection 6(f)(3)(G)) In 1964 congress placed on the registrant the ultimate burden of persuasion to show that his product meets the requirements of the law. This was upheld in 1972 in Environmental Defense Fund v. Environmental Protection Agency (150 U.S. App. D.C. at 352, 465 F.2d at 532). The U.S. Circuit Court stated, "The burden of establishing the safety of a product requisite for compliance with the labeling requirements, remains at all times on the applicant and registrant." Again in EDF v. EPA, 548 F.2d 1012 (D.C. Cir. 1976), the U.S. Circuit Court of Appeals said, "In its 1964 amendment to the Act, Congress made clear that the public was not to bear the risk of uncertainty concerning the safety of a covered poison. In the absence of an equally explicit countermanding direction from Congress, we will not force the public to assume it."

The court pointed out that information relevant to safety issues are in the possession of the manufacturer. The registrant generates all the data for submission to the government; the government is privy to all the data -- over a period of many years. To then place the burden of proof on the public after a substantial question of safety has been established is clearly unfair.

Therefore, the National Audubon Society respectfully requests you to retain the 23 years of existing law in which the congress and the courts have stated that the ultimate burden of proof must be born by the registrant to make sure that Section 505 does not implicitly shift the ultimate burden of proof concerning the safety of the pesticides.

CITIZEN SUIT PROVISION

FIFRA is now the only environmental statute that does not provide for citizen suit action. The Toxic Substances Control Act (TOSCA), the Clean Water Act, the Safe Drinking Water Act, and the Clean Air Act all provide for citizen suits to be filed. The National Audubon Society believes a citizen suit provision should be included in FIFRA as legislation is being crafted in this session. Since TOSCA is implemented by the same part of EPA, it might be logical to adopt a citizen suit provision similar to that contained in 15 USC 2619, the exact language of which is attached (A).

Other models for citizen suit provisions can be found in the Clean Air Act provision at 43 USC 7604, the Safe Drinking Water Act at 42 USC 300 (j-8), and the Clean Water Act citizen suit provision at 33 USC 1365.

INDEMNITIES

Section 1301 of S. 1516 amends Section 15 of FIFRA by requiring EPA to report to the relevant congressional committees on action that requires payment of indemnities, the reasons and the estimated cost. After these facts are provided, any indemnities must be appropriated in advance as a specific line item.

This is the same language approved by this committee in the 99th

Congress, and twice approved on the Senate floor. Since the 99th Congress when the House refused to agree to this change, the estimates for indemnities for one pesticide, dinoseb, have been as high as $130 million, a figure that dwarfs the entire program costs for pesticides. If a product is suspended with no advance warning, because of a sudden and unforseen emergency, congress can appropriate indemnities as it did for tris-treated pajamas in 1976. On the other hand, if a company produces a high risk pesticide each year, despite serious concerns published by EPA and raised by the public, the public should not have to pay the company full costs of stocks on hand simply because the company knew it would be paid.

DISPOSAL

When a registration is cancelled, the registrant can under current law require EPA to assume the burden of disposal. Under the existing indemnities provision, the company is also paid full cost plus an add-on for its suspended pesticide, including fertilizer and mixtures containing only a percentage of active ingredient. These double costs to the public threaten not only to overwhelm EPA's regulatory capability but to bankrupt the Treasury. Moreover, as Rep. Tom Coleman (R-MO) testified on the House side (June 10th), the danger to the community where the compound is stored constitutes a high personal risk to the public. Finally, disposal problems harm the image of the company even though the company may not be technically responsible for storage deficiencies.

The National Audubon Society urges congress to require registrants to submit an acceptable disposal plan at the time of reregistration. Such a requirement would encourage development of technologies to adequately resolve disposal, conversion efforts on hazardous substances to less harmful constituents, and construction of facilities to destroy, store or convert their products to recycle. Eventually, disposable or convertible products would replace current, impossible-to-dispose products and reduce the heavy burden of highly toxic disposal problems.

Section 506, - Administrative review - contains a new subsection (g), allowing "existing stocks to be used up if such use will not cause unreasonable adverse effects on the environment." In 1975 EPA decided to allow use of existing stocks after suspension of aldrin/dieldrin, and in 1978 to phase out uses after suspension of chlordane/heptachlor rather than pay indemnities.

It seemed easier to let a high risk pesticide sift through the market, dispersed around the country, with bureaucratic fingers crossed in the hope that no problems would result. But they did. A recent example was heptachlor use in livestock feed in Arkansas, which caused damages to dairy cows, beef cattle, hogs and sheep in Arkansas and parts of Kansas, Missouri and Oklahoma, exceeding $10 million in damages and loss for farmers in 1985. For risky compounds, the registrant should pay, not innocent victims or the tax paying public.

Audubon would like to add a sentence to the subsection on existing stocks as follows:

> "(3) EXISTING STOCKS.--The Administrator may permit the continued use, distribution, or sale, or any combination thereof, of existing stocks of a pesticide whose registration is canceled under this Act to such extent,

> under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.
>
> Conditions may include disposal of stocks by the registrant under terms specified by the Administrator. (Underlined section denotes new addition)

UNIFORM MARKETING

We remain firm in opposition to any constraints placed upon states to regulate pesticides within their borders. It is currently very difficult for states to take action on pesticides, and any additional hurdles would inhibit already diminished resources within the states, States not only serve as a check on EPA's fallibility, some states can act as a public conscience when EPA lacks the political will to take necessary action. States can and should serve as a barometer of public sentiment. States also provide a market niche for specialty markets for small companies that cannot compete on a national scale with larger companies.

In our view, the need for this provision has never been established. Convenience and a perception that commerce is threatened is argued, yet marketing orders currently sustain differences between federal and state specifications for fruits and vegetables. There is no chaos alleged in that sector. Some crops are regional, such as citrus, and some have regional variations, e.g., apples and potatoes. Just as marketing orders vary, so should tolerances acceptable for such produce be desirable.

Despite existing capability to set stricter tolerances, there are only two examples: EDB and Alar (Daminozide). EDB became a problem only after widespread findings of EDB residues in many foods, in many states, and after a furor over the agency's inability to conclude a chaotic regulatory review of the registration. The Alar example came after EPA allowed a highly questionable registration pending the filling of data gaps. Several states decided not to wait for completion of tests. Currently, delay rewards the registrant. The provisions supported by the House in the last session would impose cumbersome and onerous procedures for states to undergo in order to set stricter tolerances.

There is also no precedent for a uniformity provision. Most statutes expect the federal government to establish minimum standards or baselines which states may, at their discretion, determine to be more strenuous with respect to standards as well as enforcement. The Clean Air Act, the Clean Water Act, and the RCRA all allow states to be more strict. States traditionally serve as a check on the federal decision making. We cannot rely on the federal agency to be infallible. Even with all data in, and fully evaluated and validated, it is all too possible for EPA to err or bow to political pressure.

The recent study of tolerances by the National Academy of Sciences pointed out the need for consistency in federal standards, particularly old and new registrations, and raw and processed food tolerances. Federal tolerances are obviously far from consistent, reliable or adequate.

By presenting more difficulty for states to protect their citizens, confidence in our food supply can only be undermined. Public anxiety about pesticide residues in food is an impressive 77 to 98 percent, as shown in several recent public opinion polls. Thus, it would seem that to limit states' actions is the wrong thing to do at this time.

We urge you to reject uniform marketing amendments if offered in committee mark up or on the Senate floor.

LIABILITY

Differences arose in the 99th Congress between the House and Senate on whether or not to permit a liability waiver for farmers for damages caused by pesticide use. Audubon objects to any preemption of other environmental laws, and urges clarification as to where liability claims should be directed. "Responsible parties" might be acceptable if the law specifies exactly who those responsible parties will be. In any case, our underlying concern is that all persons who use pesticides should do so as responsibly as possible, and a liability waiver may not encourage the kind of personal responsibility that should accompany use of economic poisons. Label directions are not always clear, and not easy to enforce. There is essentially no substitute for personal responsibility to use these chemicals as carefully as possible. If ground water should become contaminated as a result of totally careful (and legal) use, the law of strict liability places responsibility on the registrant for problems that arise from foreseeable use. It seems to us that creating a federal precedent for liability is premature. We therefore oppose the amendment to be proposed to exempt farmers from liability unless these questions are resolved.

GROUND WATER

Of the many pieces of legislation at the federal and state level addressing ground water regulation, we will comment on why we support S. 1419, the Ground Water Safety Act, introduced on June 24, 1987 by members of the Agriculture Committee and the Committee on Environment and Public Works. In general, we favor S. 1419 on the basis of its comprehensive preventative and responsive provisions over its House counterpart, included as Section 814 of H.R. 2463.

It has become an urgent priority to regulate pesticides contaminating ground water as reliance on ground water can only increase. Over 97 percent of the drinking water of rural America comes from underground sources, In addition, 40 percent of the general population served by public water supplies used ground water in 1980, or nearly 74 million people. The growing reliance on ground water is reflected by the fact that ground water withdrawals between 1950 and 1980 increased 158 percent, while surface water withdrawals rose only 107 percent. Ground water contamination from pesticides has now been documented in 36 states.

The definition of potential sources of drinking water in S. 1419 is the same as underground sources of drinking water in the Safe Drinking Water Act. The House bill, H.R. 2463, makes a distinction between current and potential sources by considering when the water is likely to be used for human consumption. Such a distinction appears to sanction contamination of potential drinking water supplies without regard for human safety, without regard for future needs, or where states may simply declare usable ground water resources as unusable. We believe that to the extent this distinction between currently used and potentially used water sources and to the extent it focuses on contamination within wells rather than within aquifer flow systems, it sets unwise and unworkable precedents for ground water protection policy. The Senate's S. 1419 acknowledges the interconnection of ground waters with streams, rivers or wetlands, and that ground water is a part of nature's hydrological cycle. Therefore, Audubon supports the definition of underground sources of drinking water in S. 1419.

We would like to point out that while only 25 percent of ground water use in the last few years has been overdraft, almost all of the overdrafts have occurred in agricultural areas. Ground water will therefore become increasingly scarce in these regions, and it is therefore all the more important to keep it uncontaminated.

In addition, notification of a pesticide detected in ground water is to be reported to EPA, not just by a registrant. Many state agencies, university centers, water scientists, USDA, USGS, etc., may detect contamination and S. 1419 provides for other parties to so notify EPA.

After a pesticide is detected in ground water and the agency determines that there is a reasonable likelihood that the standard will be exceeded as a result of the registered use or normal agricultural practice, EPA is to impose restrictions on the use of the pesticide to prevent contamination. A presumptive trigger for these amendments is 25 percent of the standard. If more than 50 percent of the standard is detected at any site, the EPA and the relevant state are to take action to protect the health of those in the vicinity of the contamination.

In addition, EPA will provide technical assistance and information to the states and to users of pesticide products to develop management practices that will help farmers to reduce or prevent contamination. Financial assistance will be provided in grants to states. This assistance was the single most important need identified by state and local officials at a ground water workshop held last week on July 23-24, 1987 by EPA.

An important difference between the House and Senate bills is the standard for "acceptable" levels of pesticide contamination. The House section provides for maximum contaminant levels (MCLs) or if no MCL has been established, a health advisory level is used. S. 1419 provides that the standard be set at the MCL if there is no threshold for the chronic adverse health effects of the pesticide, and the MCL will not, considering other exposure, produce more than a negligible risk of chronic adverse health effects.

Standards have been an issue for some time. On the one hand, some farmers, academics, and local officials want standards to be able to measure what levels should be of concern. On the other hand, drinking water administrators, environmentalists, and public health officials fear standards, particularly those based on removal technologies, will be used to justify contamination.

The National Audubon Society believes negligible risk, as proposed in S. 1419, is a dangerous concept if it implies acceptable risk. It is unfair to those persons whose health is at risk to have regulatory acceptance of their risk. Deliberately allowing carcinogens in drinking water at any level is simply unacceptable public policy.

At the same time, the Senate amendments in S. 1516 contain no mention of ground water (except for the section 301 in which reregistration of pesticides is to give priority to active ingredients that "(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish). Ground water needs to be regulated in law now, as states are enacting strong laws, and more pesticides are being detected in ground water with increasing frequency.

Clearly, protection of ground water needs to be addressed in FIFRA. Pesticides are routinely contaminating our ground water each day as EPA suffers regulatory paralysis. Rather than stand by as nothing is done about this progressive contamination, we choose to support S. 1419 believing that a good and constructive start is urgently needed now. Our conciliatory position is dependent on inclusion of S. 1419 in FIFRA. If S. 1419 is not included in FIFRA, we will work strenuously to target ground water in comprehensive preventative legislation at the national and state levels.

We oppose the House amendments included in H.R. 2463 as fearfully inadequate. Since FIFRA amendments are intensely controversial and notoriously unpopular with the agriculture committees, substantive amendments tend to skip consecutive legislative sessions. Ground water legislation should not be postponed.

Public concern about water quality is at an all time high. A Lou Harris poll published in March 1987 found 86 percent of those polled believed that no exception should be granted for water pollution. A poll in Iowa found 83 percent of respondents feeling that more needs to be done to solve ground water pollution problems. 'Water quality is clearly a health issue and, as such, is not negotiable," was the conclusion in U.S. Water News this past spring. We agree.

PATENT TERM EXTENSION

Section 2402 of S. 1516 provides patent term extension for biotechnology products despite the lack of formal regulation for pesticides derived by DNA technology, or any reference to recombinant DNA in FIFRA. The National Audubon Society has several comments pertaining to this issue.

It seems presumptive to include biotechnology products in patent extension language when, in fact, congress has yet to address the legal issue of patenting genetically engineered organisms. The National Audubon Society encourages industry to develop innovative pesticide research to find alternatives that will diminish our current unilateral dependence on chemicals. However, to promote this new technology by providing patent protection for genetically engineered organisms is certainly putting the cart before the horse. There are substantial differences between bioengineered pesticides and chemical pesticides which must be considered before patent protection for biotechnology products is included in or associated with FIFRA.

Section 2402 provides patent term extensions for all products regulated under FIFRA, TOSCA and the Federal Plant Pest Act. While FIFRA and TOSCA are implemented by EPA, the Plant Pest Act is implemented by the Animal and Plant Health Inspection Service of the USDA. EPA intends to make health and safety data accessible for comment before registration of a biotechnology product, and to define what companies may declare confidential business information.

On July 17, 1987, EPA's Biotechnology Science Advisory Committee (BSAC) made a commitment to making premanufacture notifications and experimental use permits accessible to the public in order to increase participation in the policy process as the regulations are developed and implemented at an early stage. In addition, the BSAC noted that the agency should not be hardened by past TOSCA and FIFRA experiences so as to treat biotechnology the same way as conventional chemicals. The significant factor is public uncertainty about biotechnology releases into their neighborhoods. Without information the public suspects the worst. Disclosure is absolutely necessary to allay such fears.

On the other hand, applications for release and transport of biotechnology products under the Plant Pest Act are not required to be noticed in the Federal Register. As patent term extensions are to follow the same protocol for disclosure as the act under which the product is regulated, the public will not know that a either patent or patent term extension has been provided until after the fact. This effectively precludes the public from the decision making process, and conflicts with EPA's efforts to keep biotechnology an open issue with public involvement.

Section 2402 also states that a "'major health or environmental effects test' means an experiment or study...that requires at least six months to conduct." National Audubon recognizes the need for extensive research on health and environmental effects, but test duration is not necessarily a good indication of the quality of an experiment. Many short term tests, such as those for acute toxicity or mutagenicity, are quite reliable. Most environmental effects are generally less perceptible, and require longer term studies. Depending on the questions congress regards as necessary, the types of tests and the length of time needed for doing a study may vary. National Audubon regards the stipulation of six months for a study as arbitrary and without justification in the context of this rule.

Should patent term extension remain in this FIFRA bill, National Audubon suggests that the wording in 2402 (h) be changed to read that "the Commissioner, the Administrator and the Secretary of Agriculture shall establish such fees as appropriate to cover the costs of carrying out their respective duties and functions under this section" in order to ensure recovery of costs.

The National Audubon Society believes that biotechnology is a timely issue for congressional action. For those who may want it, a general description of the science, it's applications and its relevance to FIFRA is attached. Until congress addresses biotechnology issues directly, piecemeal provisions such as those included in section 2402 may only handicap the various agencies in their efforts.

Beyond our comments on patent extensions proposed for DNA products, Audubon questions whether or not patent term extensions are really needed in view of the provisions contained in Sections 204 and 205. Registrants appear to have automatic "patent extensions" in that no generic company can start to conduct tests until after patent expiration. Given the lag time for review of registration applications, and the amount of time for the tests to be completed, the primary registrant has a built-in patent extension even after the patent has technically "expired." These provisions in S. 1519 render

Section 2402, the patent term restoration legislation, unnecessary unless congress wants to perpetuate monopolistic practices and discourage competition. One remedy for the unintended number of added "patent" years due to provisions in Sections 204 and 205 might be to word Section 158(c)(1)(AA) as follows: "(A) the term of any patent may not be extended for more than 5 years, including time provided to the first generic company for testing and review of applications for registrations of the expired product." (Audubon's suggested addition underlined.)

CONCLUSION

Mr. Chairman and members of this committee, the National Audubon Society shares your hope that the 100th Congress will enact FIFRA amendments this year. S. 1516 should help EPA to regulate pesticides with greater resources than they have had in the past 17 years administering the law. You have provided EPA with more resources from added fees, and removed automatic payment of indemnities in case suspension is required. We request that current law be retained regarding ultimate burden of proof. We urge inclusion of a citizen suit provision. We also urge you to address disposal problems at this time. We believe ground water protection is so important, it needs to be addressed comprehensively in any legislation governing it, and thus we urge you to incorporate S. 1419 into S. 1516. We urge the Senate to reject, as it did last year, any provision for uniform tolerances. Such a provision serves to dinish public confidence in EPA at a time it needs to be improved. We also urge you to reject, again, a waiver for farmer liability which would send the wrong signals to farmers who need help in ways to reduce problems rather than absolution from problems in which they are involved. Finally, we urge that patent terms for DNA products not be summarily extended without companion legislation in the authorizing committee. We would be pleased to answer any questions and look forward to working with you in passing FIFRA amendments in the 100th Congress.

Thank you.

ATTACHMENT A: Pub.L. 94-469, § 20, Oct. 11, 1976, 90 Stat.

(a) In general.--Except as provided in subsection (b) of this section, any person may commence a civil action--

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, 2605 of this title, or order issued under section 2604 of this title to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principle place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and suppoenas for witnesses may be served in any judicial district.

(b) Limitation.-- No civil action may be commenced--

(1) under subsection (a)(1) of this section to restrain a violation of this chapter or rule under this chapter--

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 2615(a)(2) of this title to require compliance with this chapter or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this chapter or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action; or

(2) under subsection (a)(2) of this section before the expiration of

60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 2606 of this title, before the expiration of ten days after such notification.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) **General.**--(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a) of this section, may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this chapter or any rule or order under this chapter or to seek any other relief.

(d) **Consolidation.**--When two or more civil actions brought under subsection (a) of this section involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in--

(1) any district which is selected by such defendant and in which one of such actions is pending.

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

ATTACHMENT B

TO NATIONAL AUDUBON SOCIETY TESTIMONY ON S. 1516 REGARDING BIOTECHNOLOGY

By Deborah Munt

Biotechnology, recombinant DNA technology and molecular genetics all refer to the science of manipulating the genetic material of cells and their organisms and the products of those manipulations. Genetic material is found in every living cell of every living organism. It is composed of deoxyribonucleic acid (DNA), a double stranded helical molecule consisting of only four subunits. These four subunits, called nucleotides or bases, are the "alphabet" that provides a "text" of information and instructions that the cell is able to "read".

The entire complex of DNA in a cell is called its genome and represents the entire potential of that cell. Genes are segments of DNA which can either act alone in coding for a specific cell product, or can act in concert with other DNA segments as a means of coordinating a response. The underlying principle in molecular genetics which helps coordinate these events is that DNA is transcribed into ribonucleic acid (RNA) which in turn is translated into protein. Not all DNA gets translated into cell products; non-coding regions of DNA serve to regulate the entire process and are very important to the efficient functioning of a cell or organism.

Essentially, unless an organism's genetic code is understood in quite complete detail, it is impossible to predict what the effects of manipulating its DNA will be. These manipulations take the form of cell fusions, gene translocations, microinjections, "shotgunning", and other recombinant techniques which involve the deletion of DNA segments from a cell or organism as well as additions of DNA to a cell or organism. The latter could be an exchange of DNA from cells of the same species, or it could be intergeneric, meaning there is DNA exchange between two different species. The language of the genetic code is the same for all living organisms, microbial, plant or animal, which facilitates the ability to create all kinds of new organisms that do not exist in nature.

FIFRA was not written with any intent to regulate genetically engineered organisms. When the statute was enacted in 1947, the primary need was to provide rules for consistency in labeling chemical pesticides that were coming into vogue. Naturally occurring organisms were first registered under FIFRA in the late 1940s. Since then, 14 microbial agents have been incorporated into 100 registered products whose major uses are in agriculture, forestry and mosquito control.

Regulation of microbes that have natural pesticidal properties is a logical progression for inclusion under FIFRA. The Office of Pesticide Programs (OPP) at EPA has oversight responsibility over what are referred to as biorational pesticides. This class of pesticides comprises two categories: 1) biochemical agents such as pheromones, growth regulators, and other naturally occurring but synthetically produced biochemical compounds, and 2) microbial agents such as bacteria, fungi, viruses, and protozoans. The latter category includes both naturally occurring and strain improved organisms, rendering genetically engineered organisms within OPP/EPA jurisdiction.

So far the microbial organisms registered under FIFRA have not been genetically manipulated, but with the rapid advances brought about by molecular genetics, it is expected that there will be many more biological pesticides produced by the application of genetic engineering that will be presented for registration under FIFRA in the next several years.

There is a big distinction between chemical pesticides and bioengineered pesticides. Living organisms have the capacity to reproduce and spread throughout the environment. This could impact the environment on both the population and ecosystem levels. On a population level, the concern pertains to the survival and growth of the introduced organism, and its interactions with indigenous species, particularly regarding predation, habitat specificity, and competition for resources. On an ecosystem level, there is concern about changes in ecosystem processes. e.g. nutrient cycling, primary production, decomposition and respiration, as a result of the engineered organisms' activities once established. The first draws upon extensive experiences with the introduction of exotic species into the environment, while the second requires a systematic examination of ecosystem processes.

Although the microbes and the genetic manipulations performed on them may be well characterized in a controlled laboratory environment, introducing genetically engineered organisms in the uncontrolled environment of a field demands more research than is now required. Specific issues which need to be addressed are persistence in the environment, gene transfer to other organisms, and development of techniques to detect and monitor these microbes and their behavior in the environment. It is important to understand the nature of the organism, and its fate in a natural ecosystem or an agricultural ecosystem, what responses are triggered, and the significance of these changes for agriculture and the way we produce our food.

Senator **Fowler**. Ms. Margaret Seminario, associate director, Department of Occupational Safety, Health and Social Security of the AFL-CIO.

STATEMENT OF MARGARET SEMINARIO, ASSOCIATE DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY, HEALTH AND SOCIAL SECURITY, AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

Ms. **Seminario**. Thank you very much, Senator. The AFL-CIO does appreciate the opportunity to testify at these hearings on the FIFRA reform amendments. We have been involved with efforts to amend the FIFRA Act for a number of years now, and as with everyone involved, been frustrated by the inability to bring the process to a conclusion. The introduction of the Senate bill this year, which embodies the framework of agreements we have struck before and strengthens some key areas, provides hope that we will conclude the process, hopefully this year.

We have submitted a prepared statement and I would like to take a few minutes to focus my verbal testimony today on the worker safety and health problems that the AFL-CIO is particularly concerned about.

With respect to worker safety and health problems, farmworkers and pesticide applicators are probably at the greatest risk of health problems related to pesticide exposures simply because the exposure levels to those individuals is greater than the general public and also because of the nature of their work they have exposures over a longer duration.

The information that is available shows that these workers do suffer, in fact, both acute and long-term chronic effects. Because drafting of the Occupational Safety and Health Act of 1970, it has been determined, at least a legal determination was made in the early 1970's, that certain classes of workers, specifically farmworkers and pesticide applicators were outside the jurisdiction of OSHA with respect to pesticide exposure and under the jurisdiction of EPA under the FIFRA law.

Even though other workers who manufacture pesticides exposed to those same substances are under OSHA, farmworkers and applicators, indeed, are under FIFRA. When we look at the FIFRA provisions and EPA programs for workers in these areas, what we find is some limited aspects of the law do deal with worker safety and health. If you look at a pesticide label, it may contain certain limited provisions that deal with the worker safety issues.

But, in fact, EPA and the FIFRA legislation have really never been set up to deal with worker safety and health problems. The Agency has really never had a full-blown program to deal with these problems or standards in effect, and in fact, there really is no enforcement of those limited provisions that do exist because of the relationship between EPA and the States in this area.

Ideally, we in the labor movement would like to see farmworkers and applicators covered by OSHA. That may not be possible at the current time, and so failing that, what we would like to see is, whoever has the jurisdiction, provide these workers the kind of protection that they really need.

Last year's bill and this year's bill do contain provisions on worker safety and health recognizing that these workers do face serious safety and health problems. Those provisions mandate EPA to set health and safety standards for both farmworkers and applicators exposed to pesticides, recognizing EPA's failure to act in this area.

EPA, indeed, has been working on farmworker safety standards for some time. To date, nothing has yet emerged in the way of a proposal from the Agency, and so we are not fully informed as to what those proposals might be. Limited information that is available suggests that they may be inadequate in several key respects, with respect to providing farmworkers the protection they need.

One of the provisions in current FIFRA legislation, which is a real roadblock to worker protection, are the prohibitions on recordkeeping for agriculture employers. Those recordeeping prohibitions have been interpreted as meaning you cannot even require an agriculture employer to keep a material safety data sheet on chemical hazards.

Every other worker in the United States will be guaranteed the right to know that information because OSHA provides that and will be expanding that protection. Agriculture employees exposed to pesticide, if this recordkeeping prohibition stands, will not have a right to know that basic information, and we think this inequity should be remedied, and that, indeed, the legislation should be modified to allow the basic safety and health measures be put in place.

The AFL–CIO believes that the current legislation could be strengthened in the worker safety and health area, not only mandating that standards be set, but outlining the specific kinds of protective measures that should be followed, including the establishment of field reentry periods. The legislation should contain provisions which would prohibit employer discrimination against workers who exercise their rights under this law.

This is the same kind of protection afforded other workers. It is not new for Congress to legislate standards. They have done so in the past in the mine safety and health area, and recently, last fall, did so with respect to hazardous waste workers. They mandated that OSHA issue standards and outlined the specific requirements of the standard in legislation, and we would urge that this legislation do the same for farmworkers and applicators.

Again, we commend the committee for introducing S. 1516. We think it is a step forward, and we look forward to working with the committee on this legislation.

[The prepared statement of Ms. Seminario follows:]

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TESTIMONY OF MARGARET SEMINARIO, ASSOCIATE DIRECTOR, DEPARTMENT OF OCCUPATIONAL SAFETY, HEALTH AND SOCIAL SECURITY AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS BEFORE THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE ON S. 1516, THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT REFORM OF 1987

July 30, 1987

Mr. Chairman, the AFL-CIO appreciates the opportunity to testify before this Committee on legislative reforms to improve the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The need to reform FIFRA is universally recognized. The re-registration provisions of the current law have failed to generate testing of pesticides in a timely fashion. Cancellation procedures are cumbersome. The hazards of inert ingredients are inadequately addressed, and no provisions are made for protection of workers exposed to pesticides even when hazards are well documented.

Despite the widespread agreement that the FIFRA law needs to be updated and reformed, reaching closure on a series of legislative initiatives has proved to be an elusive goal. In 1982, labor and public interest groups did reach a tentative agreement with representatives of the agricultural chemical industry on legislative reforms. However, the agreement was short-lived. That year pesticide reform legislation did pass the House, but was never brought to the Senate floor for a vote.

During the 99th Congressional session, once again serious efforts were made to reform FIFRA. Lengthy negotiations between a coalition of public interest, environmental and labor groups, the agricultural chemical industry and farm groups produced a compromise FIFRA bill that would have significantly improved pesticide health and safety protection. Among the key aspects of the agreement were provisions to: (1) expedite re-registration of existing pesticides by imposing strict deadlines for submission of health effects data and for evaluation and registration by Environmental Protection Agency (EPA); (2) ensure public access to pesticide health and safety data; (3) prevent groundwater contamination; (4) require improved standardized training for pesticide applicators; and (5) improve protections provided workers exposed to pesticides during application or in agricultural work.

Even though both the House and the Senate passed legislation last year that contained the basic elements of the core agreement, FIFRA reform legislation died on the last day of the 99th Congress as a result of controversial amendments that were not a part of the compromise agreement. Two of those amendments--one that would have relieved pesticide applicators of liability, and another that would have pre-empted states from setting three stricter tolerances for pesticide residues on food--were amendments that the AFL-CIO opposed.

Mr. Chairman those of us who have participated in two unsuccessful efforts to amend FIFRA recognize that it is difficult for all involved to come back and make a third attempt. But try we must. The environmental and health problems associated with pesticide use and exposure are too serious, and the gaps in the law too significant to be ignored. Pesticide contamination of groundwater and residues on food put millions of Americans at risk of disease and threaten the environment. Indeed a recent report of the National Academy of Sciences estimates that as many as 1.46 million cancers may result from residues in food of 28 commonly used pesticides.

For exposed workers, pesticides pose significant health problems about which the AFL-CIO is particularly concerned. Those who work with pesticides are often at the greatest risk of exposure. Pesticide applicators, workers who must re-enter fumigated work areas before the vapors are adequately dissipated, and those who handle fumigated commodities are at the greatest risk. These include workers in the grain and flour industries, public employees, and farmworkers.

Agriculture is among the most dangerous occupation in the United States today as measured by work-related deaths and disabling injuries. Nonetheless, farmworkers are virtually unprotected from pesticide hazards under current federal law. The 2.7 million farmworker adults and children who toil in our nation's fields and put food on our tables do not even have the right to know of the health hazards caused by the pesticides with which they work.

Some pesticides are so poisonous that as little as a few drops of the concentrated substance absorbed through the skin can kill a worker. Besides acute illness and injury from pesticides, farmworkers run the risk of chronic health problems like cancer, birth defects, and nerve damage from pesticide exposure. When they do develop chronic illness or their children are born with birth defects, neither they nor their doctors can obtain from the grower the names of the products to which farmworkers were exposed because growers, outside of California, are not required to keep records of the pesticides they apply on their land. Consequently, we do not now know the full range of long-term effects of pesticides on farmworkers.

Nor does EPA fill the gap. Currently EPA regulates human exposure to pesticides based primarily on the acute toxic effects of these chemicals. Thus, EPA now permits the use of many pesticides even though it lacks any data on the carcinogenicity, teratogenicity or mutagenicity of these products.

Currently, there are also no federal requirements that fields be posted with information stating what pesticides have been sprayed or when it is safe for workers to re-enter the fields. As a result farmworkers are needlessly poisoned because they are directed to enter fields before it is safe for them to do so. Unfortunately, farmworkers are not in a position to protect themselves from this abuse. Deprived of training on health and safety and of information on specific pesticide applications, they do not know when it is harmful to re-enter a field.

Provisions in the current pesticide law which restrict recordkeeping by agricultural employees are a major impediment to the development of health and safety standards for farmworkers. The recordkeeping restrictions have been interpreted as precluding requirements to maintain safety data sheets on chemical hazards, and to keep records of pesticide exposures. As long as these recordkeeping restrictions exist, it will be impossible to afford farmworkers the protection they need.

Farmworkers are also at a disadvantage compared to other workers because presently there is no anti-retaliation to protection in FIFRA.

Therefore, when farmworkers complain to their employer about being sprayed with pesticides or poisoned through exposure to pesticide residues--and these incidents are all too common--they run the very real risk of being fired.

Farmworkers, however, are not the only workers left unprotected from dangerous pesticides. Take the nonagricultural workers, such as the workers employed in this nation's 11,000 grain elevators, feed mills and flour mills. These workers apply thousands of tons of pesticides to grains, work in grain bins and other confined spaces recently treated with pesticides, and must often handle treated grains and flours. Often these workers have no warning that they are about to be exposed to dangerous chemicals such as methyl bromide or phosphine gas. A recent General Accounting Office report that evaluated worker exposure to pesticides in this industry, "Grain Fumigation: A Multifaceted Issue Needing Coordinated Attention," (September 1981), concluded that grain workers continue to be exposed to potentially unsafe fumigant levels because of improper application procedures, inadequate training of workers, and failure to post and provide warnings in fumigated areas.

The same exposure problems holds true for the hundreds of thousands of public employees that routinely use pesticides on the job. Road workers spray roadsides to destroy encroaching weeds, park workers spray picnic and playgrounds, grounds keepers spray school and hospital grounds, and custodians spray pesticides inside buildings to exterminate cockroaches, termites and other pests. In addition to the applicator, indirect exposures also affect the health of other employees who work in pesticide treated areas.

The applicators are oftentimes not professional applicators, but workers given a bucket and simply told, "apply this pesticide." Frequently no information is given on the pesticides being applied. Rarely are signs posted warning other workers that the area is being treated, and applicators are given almost no training on potential health and safety effects of the pesticides.

Despite the significant exposure and health risks posed by pesticides, farmworkers and pesticide applicators are not afforded the same protection from pesticides that all other workers in this nation have received since 1970.

Language in the Occupational Safety and Health Act has been interpreted by the courts and by the Occupational Safety and Health Administration (OSHA) as pre-empting the application of that law to farmworkers and applicators with respect to pesticide exposure. Those workers have had to rely upon FIFRA and EPA for legally mandated protections. Unfortunately, EPA has done little to assert its jurisdiction in the area of worker safety and thus pesticide applicators and farmworkers are still largely unprotected.

The AFL-CIO believes that the health and safety protections of farmworkers and applicators exposed to pesticides should be under the jurisdiction of OSHA. Despite the problems with the administration of that program, the regulatory and enforcement authorities available to OSHA make it better suited to address worker health and safety concerns.

However, even if these workers remain under the jurisdiction of FIFRA for pesticide exposures, they should be afforded no less protection than other workers exposed to pesticides.

Seventeen years after Congress guaranteed all American workers the right to a safe and healthful workplace, EPA has failed to take action to protect farmworkers and applicators. Because of this inaction, we believe that FIFRA reform legislation must mandate protective standards for these workers which require specific protective measures, and training requirements. Standards should provide for protective clothing, medical surveillance, training on hazards and protective measures and appropriate re-entry periods to avoid harmful exposures. The legislation must also mandate strict training and certification procedures for pesticide applicators, such as the provisions which were included in last year's legislation. Workers who exercise their rights to seek protection from the employer or the goverment must be protected against retaliation or discrimination.

Congressional action requiring the adoption and implementation of worker protection measures for specific hazards is not new. Indeed there is a history of Congressional intervention when administrative agencies have failed to do their job. In 1977, the Congress set statutory limits on the amount of coal dust permitted in mines. Last year, as part of the Superfund legislation, Congress directed OSHA to adopted standards, containing specific protective measures for hazardous waste workers since OSHA had failed to take action to protect these workers.

Applicators and farmworkers exposed to dangerous pesticides need the same level of protection and the same kind of Congressional attention.

The AFL-CIO believes that S. 1516 introduced by members of the Committee on Agriculture is a major step towards reforming FIFRA. The framework of the legislation follows the agreement reached last year between the environmental, labor and public interest coalitions and other parties. In addition, the Bill contains additional strengthening provisions which the AFL-CIO supports that would increase the fees to pay for the reregistration of pesticides and requires a specific Congressional appropriation for the indemnification of holders of a pesticide product which is superseded or cancelled.

We believe, however, that the legislation can be further strengthened in key areas such as worker protection, citizen enforcement rights, and groundwater provisions. For the worker protection provisions, we believe the Bill should set forth the protective measures to be included in health and safety standards, including the establishment of field re-entry periods and should prohibit employer discrimination against workers who exercise their rights under this law. In addition, the legislation must require basic records to be maintained on pesticide use and hazards for worker protection measures to be fully effective.

The AFL-CIO looks forward to working with members of this Committee towards the final passage of FIFRA reform legislation that will protect workers, the public and the environment against the hazards of pesticides.

Senator **Fowler**. Thank you very much, Ms. Seminario. I think we got a clear—I did, at least—a clear understanding of what your top priority—worker health and safety—would be. I wonder if I could ask the other two panelists if they rated these in any way, the one thing that is unquestionably our top priority for change in this year, given the timetable that you have all acknowledged and the deadlines that we are under, that we ought to concentrate on even to the exclusion of others, if necessary?

Ms. **Hathaway**. We would rate elimination of indemnification and improving the disposal authorities at the very top. Citizen suits also should be in that priority list and worker protection, as well. Then resisting the weakening amendments that may be offered to preempt State authorities. Those are our highest priorities.

Senator **Fowler**. Ms. Hinkle.

Ms. **Hinkle**. How many do I get?

Senator **Fowler**. I am sorry.

Ms. **Hinkle**. How many do I get?

Senator **Fowler**. How many priorities?

Ms. **Hinkle**. Yes. How many wishes? If I had one priority it would be ground water. I think that S. 1419 is ready to be incorporated and included in S. 1516. And disposal, I think disposal is conspicuously absent, and the way is paved. It is not as though it would be an uphill battle. I am aware of the time involved, and so other than what you have in the bill that is what I would ask for.

Mr. **Meyerhoff**. Senator, if I could add something. My name is Al Meyerhoff, and I am here from California. I wanted to just raise a caution.

Senator **Fowler**. Did you just wander in?

Mr. **Meyerhoff**. No; I'm here on behalf of NRDC.

Senator **Fowler**. Good. Well, we welcome you.

Mr. **Meyerhoff**. I am sorry that Senator Wilson had to leave because I wanted to address my remarks particularly to what the effect of the preemption amendment that has been suggested would have on his own State, our State's pesticide program. We have in California the Birth Defect Prevention Act of 1984 passed overwhelmingly by the California Legislature and signed by Governor Deukmejian. It attempts to deal with the data gap issue, the failure to test pesticides. Our State acted where the Congress has failed to act in the past and hopefully will remedy that failure this session.

The preemption amendment that is being suggested is a bombshell directed at California's regulatory program for pesticides. Preemption has historically been the death knell for FIFRA reform. In 1982 the bill was killed in the Senate; and that is what got us in trouble last session as well. Preemption again is a problem this year. If this amendment were to be offered and were to be successful, I think it would kill the bill this year because it would destroy California's testing program. Statements by others that the amendment only required cooperation by California are simply false. Our program in California is a very simple one. It gave the chemical industry until March of this year to begin testing its products where data gaps existed. And where they failed to do so, and they did so fail, then the State of California conducts the tests and taxes the industry. We are in court enforcing that law, I might add.

This month 25 chemicals will be taxed, and the testing will begin, and every month another 25 chemicals will be tested and taxed for the 200 most widely used pesticides in the State. In short, we are accomplishing reregistration in California, and it would be a major disservice to public health and to my State, and I think to the country to preempt that law. I would hope that the committee and the Congress will stay clear of seeking to preempt either our testing law, our right to in California and other States to protect our food supply, or any other health matter. Thank you.

Senator **Fowler**. Well, I appreciate your testimony, and I will make sure that both Senators from California are made aware of the comments. Before I recognize my friend from Missouri, the junior Senator, Mr. Bond, let me just ask a couple of quick follow-up questions. I take it, but correct me if I'm wrong, that most of you seem to be preferring the Senate bill over the House bill?

Ms. **Hathaway**. Yes.

Ms. **Hinkle**. Yes.

Senator **Fowler**. Is that correct?

Ms. **Hathaway**. Yes, we definitely are. Yes, that is correct.

Senator **Fowler**. But are there provisions in the House bill that are not currently in the Senate proposals that you support and that we ought to look at for possible inclusion in our bill?

Ms. **Hathaway**. At this point, the Senate bill is superior in every regard. With regard to the provisions that you have, most of them are identical to the House bill. But there are a few that you have that are superior, and those are fees, disposal, and indemnification. We commend you for having the better bill this time.

Ms. **Hinkle**. You do not have disposal. You have a section on containers, but actually you do not have disposal in this bill. But it needs to be put in.

Ms. **Hathaway**. All I wanted to point to concerning disposal is a provision that you do have in your bill which allows the EPA to require of anyone who is a registrant information about where they are holding pesticides that have been either suspended or canceled. That is an important improvement of the disposal authority. But it certainly does not go far enough, and we would support enhancing that authority to include a recall provision.

So I do not want to imply that we think that your disposal provision goes quite far enough. It does not.

Ms. **Hinkle**. Sorry. That is all I was trying to point out.

Senator **Fowler**. Senator Bond.

STATEMENT OF HON. CHRISTOPHER S. "KIT" BOND, A U.S. SENATOR FROM MISSOURI

Senator **Bond**. Thank you very much, Mr. Chairman. I regret that other committee hearings have delayed my arrival at this very important hearing. I wish to enter a prepared statement in the record. I commend our chairman, Senator Leahy, for his prompt attention to this extremely important issue, and I would also ask permission to submit for the record a letter written by Governor Ashcroft of Missouri.

Governor Ashcroft has written the Senator saying that he believes that an amendment providing for uniformity as a part of the

FIFRA legislation would greatly facilitate interstate agricultural commerce. He goes on to state, and I quote, "We in Missouri do not want agricultural commodities marketers to be met with a myriad of state requirements relating to allowable levels of pesticides in and on food. National pesticide tolerances, developed through careful testing to ensure their scientific defensibility, would allow Missouri's agricultural commerce to be carried out in a more orderly manner."

And he further states that he feels it "would pose no great threat to Missouri's rights to set pesticide standards." He proposes to allow States to petition the Federal Government for acceptance of a State requirement or prohibition where unique local conditions require special attention.

Senator **Fowler**. Without objection, your prepared statement and the letter from Governor Ashcroft will be made a part of the record.

Senator **Bond**. Thank you.

[The prepared statement of Senator Bond and Governor Ashcroft's letter to Senator Leahy follow:]

STATEMENT BY SENATOR CHRISTOPHER S. BOND (R-MO.)
BEFORE THE SENATE AGRICULTURE, NUTRITION, AND FORESTRY COMMITTEE
THURSDAY, JULY 30, 1987, 11:00 A.M.

MR. CHAIRMAN, I would like to commend you on holding this important hearing to discuss the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As you know, my home state of Missouri is well endowed to support a very diverse agricultural sector. Therefore, many of the provisions of FIFRA affect a broad base of Missourians.

Although a new member of this Committee, I look forward to the challenge of developing comprehensive FIFRA legislation. As I understand it, FIFRA has been debated many times since its enactment in 1947. In fact, I have been told that a large package of amendments was nearly passed as recently as the 99th Congress.

Mr. Chairman, you are to be commended for beginning the debate on this legislation at such a date that the possibility of enactment is greater than ever. It is apparent that there is a real need to update the provisions of FIFRA and I believe that all the players are willing to cooperate in this effort.

After becoming involved in the FIFRA issue, I have been surprised by the complexity of the issues involved. Provisions such as indemnification, reregistration, liability, data compensation, patent term extension, groundwater, and uniformity are extremely important issues which affect millions of Americans.

Mr. Chairman, at this point I would ask that a copy of a letter from the Governor of the State of Missouri, John Ashcroft, be inserted into the record. The letter expresses his support of a National Uniformity Amendment.

Again, I thank the Chairman for scheduling this hearing and I am looking forward to hearing the testimony of today's distinguished witnesses.

EXECUTIVE OFFICE
STATE OF MISSOURI

JOHN ASHCROFT
GOVERNOR

June 1, 1987

The Honorable Pat Leahy, Chairman
Senate Agriculture Committee
United States Senate
Washington, D.C. 20515

Dear Senator Leahy:

It is my understanding that the Senate Agriculture Committee will be considering a uniformity amendment as part of the FIFRA legislation concerning pesticide residues in food and agricultural products.

I believe such an amendment would greatly facilitate interstate agricultural commerce. We in Missouri do not want agricultural commodities marketers to be met with a myriad of state requirements relating to allowable levels of pesticides in and on food. National pesticide tolerances, developed through careful testing to ensure their scientific defensibility, would allow Missouri's agricultural commerce to be carried out in a more orderly manner.

I feel that such an amendment would pose no great threat to Missouri's rights to set pesticide standards. If it allows states to petition the federal government for acceptance of a state requirement or prohibition regarding pesticide residues and allows exemptions to federal standards for states where unique local conditions require special attention, the amendment would give states the ability to strengthen federally established requirements and prohibitions.

Again, Senator Leahy, I believe a national uniformity amendment would serve the best interests of Missouri's agricultural commodities marketers without compromising our state's rights. It deserves serious consideration for passage.

Sincerely,

GOVERNOR

cc: Senator Bond

P.O. BOX 720 JEFFERSON CITY, MISSOURI 65102

Senator **Bond**. Given the view of the Governor of my State, I would ask Ms. Hathaway, Ms. Hinkle, and Ms. Seminario whether they feel that in this area, the regulation of interstate commerce general principles of regulation, where there is a nationwide interest, should not be established? Second what would your views be if you wish to have the States as laboratories, if they established standards which were different from, and not perhaps as strict as, the Federal standard?

Ms. **Hathaway**. We believe that the current situation under FIFRA that enables States to have more stringent pesticide tolerances and more stringent regulations with regard to pesticides works extremely well.

There should be a Federal baseline. There needs to be one. In many instances the States will completely defer to the Federal standard and feel that works adequately. In some instances they will learn that the Federal Government has not carried out its task well enough and is not protecting public health. In those instances, the States should be free to establish more stringent tolerances or to take other regulatory action. They have exercised the authority that they have now only twice, in the most extreme kinds of circumstances—with regard to the ethylene dibromide problem and with regard to daminozide, or alar, which is used on apples. Both are very serious and potent carcinogens, and both pose particularly severe problems for children.

States have been extremely restrained about exercising this authority, and we feel that they should continue to have it. It will often prompt the Federal Government to work well with the States to ensure that there will be consistent approaches taken throughout the country. But to eliminate their authority altogether would mean that the Federal Government could essentially turn a deaf ear to the State complaints and concerns about a pesticide such as daminozide and refuse to act, and there would be absolutely nothing a State could do to protect its own citizenry.

Senator **Bond**. You think there is nothing then. But on the other hand, you think that there is nothing that the States should be permitted to do if, perhaps, its research, investigation, and consideration of all of the implications of the use of pesticides would indicate that the Federal standards are too stringent? In other words, it is a one way street? So long as there is stronger regulation, you are for it?

Ms. **Hathaway**. Well, I do not think that notion is as anomalous as it may sound. The reason why we do have a Federal pesticide program is that we do need a baseline to be set. It is like every other health and safety law. We set a baseline at the Federal level, and States can go further. We would not want States to become havens for misusers of pesticides or for people who sell pesticides that are not registered or are not safe. That would be the result if we allowed certain States to be subject to the lobbying, in effect, of certain manufacturers who would say, we will move our business to your State but only if you will modify and weaken your pesticide regulatory program.

It was a basic concern that led to the Federal environmental laws being structured in this manner where there is a baseline at the Federal level, but more stringent activity could occur in the

States. Because there clearly will be efforts by some industries and certainly not all to find a way to weaken the State control, if they can.

So, setting a Federal baseline is something that you have consistently done in the health and safety areas and we do give our support.

Senator **Bond**. Ms. Hinkle and Ms. Seminario, would you care to comment on my questions?

Ms. **Hinkle**. Yes, thank you. I do not think a case has been made that interstate commerce has been harmed by the two incidents in which the States took an action that was stronger than the Federal EPA.

Second, there is room for variability among the States existing in marketing orders currently, and that has not harmed interstate commerce at all, and this is at the demand and request of the growers themselves in regard to vegetables, citrus, and other fruits.

The third point is, that tolerances are normally established on the average, very high, and I am not aware of any State that even wants to establish a tolerance that is higher than what the Federal Government has established.

Senator **Bond**. Ms. Seminario.

Ms. **Seminario**. I would just say that I agree with both the previous speakers, and that if you do, in fact, look across the board at all the other Federal health and safety laws you see that the philosophy basically has been to set the Federal minimum baseline and then to allow the States to go beyond it where they feel there is a particular need that the public health, worker safety and health, needs that further action, and they have that ability to do so. Again, we see that there is really no need to depart from that long-established principle that seems to have worked over the years, and has not been really abused. There is not really any evidence that, one, there has been abuse; and two, that there really has been a problem created by the limited actions that the States have taken.

Senator **Bond**. Thank you for your discussion. Thank you, Mr. Chairman.

Senator **Fowler**. Thank you all, panelists, very much for your participation. Last, but not least, we have Mr. Ralph Nader, no occupation listed. [Laughter.]

Washington, DC. Mr. Nader, we welcome you as always. Of course, your prepared statement will be made a part of the record.

STATEMENT OF RALPH NADER, WASHINGTON, DC

Mr. **Nader**. Thank you, Senator.

Senator **Fowler**. You may proceed as you wish. We have about 15 or 20 minutes here before we have to quit.

Mr. **Nader**. Thank you very much, Mr. Chairman, Senator Fowler. I would like to summarize my statement with a preface that comments on the inadequate level of urgency about pesticide poisoning in this country reflected in the performance of the EPA and the inadequate FIFRA statute which over the years has been a prototype for our designation as a no-law law. That is a law that purports to regulate, constrain, disclose, warn, but does very little of the sort because of very serious defects in the drafting of that legislation as well as the weakened willpower, especially in recent years, in enforcing the law.

First, I think the Congress should establish a policy that it is the goal of this country to phase out pesticides, fungicides and herbicides containing synthetic chemicals from agricultural and household use in our Nation. All over the country we have data showing serious contamination of drinking water, ground water, food, serious contamination of workers, pesticide applicators, homes. 1.5 million homes are contaminated with chlordane every year.

We also have more evidence recently about the contamination of the food that the most sensitive people in our society eat, infants and children. Infants eat a lot of apple sauce and drink apple juice, and they have been drinking and eating with alar contaminated products. They are far more sensitive to alar than adults, and a new recent National Academy of Sciences' report on alar indicates just how hazardous that chemical is to the public health.

Let us just put this in very clear focus. Let us say that Members of Congress were asked to pit the public interest in the safety of breast milk for millions of infants against the use of pesticides. Let us just make that kind of contrast and refer to not only former EPA studies, but recent studies by Colorado State University scientists, based on a national sample, found a staggering 90 percent incidence of DDE, which is a DDT metabolite, in the breast milk of humans. An earlier study by the same team in 1981 showed a 74 percent incidence of oxychlordane and other pesticides in human breast milk.

Oxychlordane is a metabolite of chlordane, which may be severely restricted shortly and finally, after many years, by the EPA. So what we are having here is a situation where millions of infants are feeding off their mothers with breast milk that is poisoned by the reckless use of pesticides which have not been adequately tested or regulated.

On the other side, we have the economic interest asserted by the agribusiness industry in the continued use of these pesticides. But how effective are these pesticides? Increasing studies show that the pests are speeding up their genetic resistance to these pesticides at an alarming rate. I will include an article recently published in the Economist, Mr. Chairman, entitled "How Bugs and Pests Rout the Chemists" for inclusion in the record.

Senator Fowler. Without objection.

Mr. Nader. Indeed, what we are seeing here in terms of resistance is almost a geometric increment where the chemists cannot keep up with the resistant capability of insects and other alleged pests.

For example, there is now a Colorado beetle that is almost invincible to the pesticides that are used against it. We are also seeing a dramatic speed-up in the time of mutation which leads to the resistance. EPA data shows a multiple increase in the last 20 years in the number of species that are resistant to one or more of the pesticides.

So we have the pesticides being less and less effective, the insects being more and more resistant, the natural predators being knocked out by the pesticides, and the chemical industry frantically trying to develop more powerful pesticides.

We are losing more of our crops to pests than ever before which means we are losing ground. That is why I think there should be a national policy expressed in this legislation to phase out this industry in favor of more effective and less damaging ways of controlling pests. More effective is defined, one, in the ways some farms and other agricultural enterprises are dealing with the problem successfully around the country, and two, to enhance and accelerate research in biological controls and other ways to control these menaces.

As far as the legislation is concerned, I think an expression both of urgency and protection of public health would be implemented if the legislation bans outright at least five pesticides by name that have been languishing in the bowels of the EPA far too long. It has been 15 years since the Congress first directed the EPA to reregister the Nation's pesticides and these five which I have selected based on the evidence against them are leading candidates: aldicarb, alachlor, daminozide or alar, captan and chlordane.

They should be banned legislatively. Now there are times when the Congress gets fed up with the regulatory agencies' delays and enacts specific bans. This was done in the 1970's when the Congress stopped waiting for the auto safety agency to issue a fuel tank standard, following reports of fuel tank rupture and incineration of victims. So they, in effect, legislated it. That will send a signal to the bureaucracy that the Congress can make its decision for the Agency using the bureaucracy's own evidence against the product.

Furthermore, I think the legislation S. 1516 opposing the preemption of State standards is wise for the reasons you have heard.

Second, I do not think there should be any special interest immunity from liability whatsoever. The common law of 50 States declares that those who cause damage will pay to compensate for the injuries.

As a result, I do not think agribusiness should be immune from any suits. I think if they are, their risk taking capability with these pesticides will be increased, and they will not be as alert to hold their suppliers and their chemical companies' feet to the fire to be more careful in labeling and in the amount they advise farmers to apply to their crops.

As you know, there has always been an exaggerated amount in many of these pesticides urged on farmers to use on their crops, both in terms of bulk and frequency.

Third, indemnification, that is a provision that needs to be deleted, and most people agree, although in this bill there is a provision for specific line item appropriations.

If a company has pesticides which are held by the EPA to be dangerous, the public should not pay for that inventory. There is a problem, however. Where is that inventory going to be stored? There will be an incentive to dump it surreptitiously, ship it abroad to the natives in the Third World who do not know about its danger, or otherwise damage the environment and the people in it.

So I would suggest that Senators consider, Mr. Chairman, a Federal facility which deals with the storage and/or destruction safely of these pesticides and herbicides and fungicides. You remember when there was a deadline a few years ago under Superfund. There was a rash of midnight dumping by these companies using unsavory third parties. For example, the chemical companies, as the New York Times reported it, in New Jersey would ship them up to Connecticut and Massachusetts at night. They would be dumped in ravines and streams for innocent people to be harmed by.

And I think that there is sometimes a very bad backlash to prudent and proper regulation in terms of turning the disposal into an underground illegal activity, and the Government should pick it up on the other side with a Federal facility which will track, locate, store, and/or destroy these substances.

Fourth, exports of banned pesticides. What companies are doing is legally exporting pesticides that are illegal in this country. The pesticides are applied on bananas, coffee, and other products in foreign countries and shipped back to our dinner and breakfast tables. This is not something that even an animal at the lower end of the ladder of evolution would do.

I know of no dog or cat who would do this. It is one of the most ridiculous, stupid, ignorant, harmful exemptions in our safety laws repeatedly found in one law after another which says, okay, companies you cannot sell it to Americans, but you can ship it overseas, such as automobiles, if indeed we had an export market these days for automobiles.

Unfortunately, unlike unsafe automobiles, food contaminated with U.S. pesticide exports bounces back to our markets for consumption, and there should be much stronger restrictions on these exports than are indicated in this bill which, in turn, is better than the present situation.

Fifth, citizen suits. Again, citizen suits are a very good display of legal vigilance, prodding. They are used in the clean water area. There are hundreds of these suits now dealing with unlawful observance of water pollution permits by companies around the country. These lawsuits are brought by NRDC, New Jersey Public Research Group, and others who are very good supplementary private sector enforcement. There should be clear citizen suits operating here, similar to section 505 of the Clean Water Act.

Six, right-to-know and adequate recordkeeping. This is something that will continue to inform and properly alarm the public so it can demand stringent enforcement. You remember on April 4, there was a fire at a pesticide warehouse in Minot, ND which resulted in the evacuation of 10,000 people. We very much need a 30-year recordkeeping requirement incorporated into FIFRA for protecting workers and consumers.

A similar concept was recently applied to EPA's regulations on asbestos abatement activities. Other right-to-know issues relating to FIFRA include full disclosure of chronic health effects on the product label as well as the health effects not yet completely tested.

I mean there is a reason why many farmers and their families have a much higher cancer rate than the rest of the population. It is because they are very much exposed to inadequately warned pesticides in their business.

Seven, require health and efficacy studies. Imagine FIFRA does not really mandate efficacy studies. There are so many exemptions here that is a very porous provision to say the least. If a company is going to sell a farmer a pesticide, it ought to provide up-to-date efficacy information. Otherwise why would a farmer want to use temik or some other pesticide if it is shown year after year not to get rid of the ants? If it is shown year after year to get into more human beings' bodies? I think pesticide efficacy is more fraudulent in the way it is sold than cosmetics, which sell hope. Pesticides sell cancer. So I think we really need to crack down on that. That is one of the greatest commercial hoaxes in our country, the exaggerated efficacy allegations of exaggerated application instructions by the chemical companies for their pesticide.

PATENT TERM RESTORATION

Usually I am opposed to any extension of patent terms. But here is where we can turn corporate greed to our advantage, Mr. Chairman. Any patent term extension should be in exchange for strong citizen enforcement tools and mechanisms as well as the proposals which I have outlined to strengthen the FIFRA legislation. It should by no means be given away without high level reciprocity to advance the public health.

A final point may surprise you, Mr. Chairman, and that is that these hearings under congressional rule will only be printed to the level of 300 volumes. There is an increasing restriction of the availability of information in congressional hearings and reports underway as well as an increasing restriction on the compilation of data and reports available to the American people by the executive branch under the Reagan administration.

I hope that you and other Senators will pay attention, along with members of the Joint Committee on Printing, to the need to avoid making taxpayers pay twice for the information that Congress assembles and produces for public knowledge. Thank you.

[The prepared statement of Mr. Nader and the article, "How Bugs and Pests Rout the Chemists," follow:]

TESTIMONY OF RALPH NADER, REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, BEFORE THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY, U.S. SENATE, JULY 30, 1987

Mr. Chairman and distinguished members of the committee, I want to thank you for the opportunity to testify today on this important legislation, S. 1516, The Federal Insecticide, Fungicide and Rodenticide Act.

Mr. Chairman, twenty-five years ago Rachel Carson inspired a generation of Americans to a new level of environmental and public health consciousness. Today after the enactment of a wide range of laws to protect the environment and public health, virtually every American still risks the effects of exposure to the widespread use of 2.6 billion pounds of pesticides a year. These chemicals come to most Americans in the form of residues on our food or contaminants in our drinking water. Too many Americans are also exposed to dangerous pesticides in the air within their homes and where they work.

Pesticide reform legislation is a fundamental law and order issue that should not be denigrated by any lowest common denominator arrangement in Congress. Too much is at stake in the integrity of the law and its management of widespread chemical violence upon infants, children and adults to warrant any further legislative cosmetic makeup.

For example, approximately one third of all fruits and vegetables grown in the U.S. are treated with a class of fungicides known as EBDCs. Through food processing or cooking EBDCs break down into a known carcinogen, ETU (ethylenethiourea). Environmental Protection Agency (EPA) documents state that the "entire U.S. population is potentially subject to dietary exposure to ETU."

Furthermore, EPA has found at least 23 pesticides in the groundwater of 24 states. Pesticides were reported in one quarter of the 45,000 water samples taken. About half of these (5,000) exceeded health guidance levels. Half of the total population of the U.S. and 90 percent of the rural population rely on groundwater for their drinking water supplies.

Other populations exposed to pesticides include hundreds of thousands of farmworkers, who are not protected under the Occupational Safety and Health Act (OSHA), and commercial applicators of pesticides and their customers. According to EPA more than 1.5 million people have been trained to handle "restricted use" pesticides since 1978. The National Pest Control Association estimates that at least 1.5 million homes a year are treated with termiticides, mostly using the notorious carcinogen, chlordane, which has been banned for home use in New York and Massachusetts. Just last week the state of Texas banned all over-the-counter sales of chlordane.

Of the 600 active ingredients that are used in the 60,000 registered pesticides, 496 are listed by the Food and Drug Administration (FDA) as having food residue potential. In May of this year the National Academy of Sciences reported that EPA believes 90 percent of all fungicides, 60 percent of all herbicides and 30 percent of all insecticides may cause cancer. Yet EPA can only cite three instances when it denied the use of a pesticide because of the supposedly restrictive Delaney Clause in section 409 of the Federal Food, Drug and Cosmetic Act (FDCA). And the General Accounting Office (GAO) reported last year that the FDA is not adequately monitoring or enforcing the FDCA to protect the food supply. The study revealed that the FDA multi-residue tests were unable to pick up 41 percent of the pesticide residues. And while 25 percent of our fresh fruit comes from abroad, the GAO also found that the FDA is only monitoring one percent of imported foods.

Since the 1972 reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA has failed to fully reregister any of the 600 pesticide active ingredients. This failure, along with the inability to expeditiously cancel known dangers such as chlordane and the years taken to cancel EDB, indicates a breakdown in public health protection of staggering proportions. The American people have become guinea pigs for the chemical industry while the regulators and Congress mildly mediate the merits of restricting these chemical toxins.

The urgency of strong legislation is self evident. I direct your attention to the handwriting on the wall: DBCP is increasing in the groundwater in Fresno County, California, eight years after it was banned; the National Cancer Institute reports farmers exposed to herbicides had a six-fold increase in cancers; and, toddlers today are eating fruit, juices and baby-foods known to contain carcinogenic pesticide residues such as daminozide.

The FIFRA amendments introduced by Senators Leahy and Lugar on July 21, 1987, represent an improvement over the present FIFRA statute. However, the bill still lacks critical provisions which are fundamental to the protection of the public's health and well-being. It is unfortunate that FIFRA reform proposals under consideration by the Congress do more to protect the economic health of the chemical manufacturing industry than they do to protect the physical health of farmers, applicators and consumers.

The choice before this Congress should be clear. Will it continue to bend to the will of the pesticide industry or stand tall to stop the cancer assault being perpetrated against the American people? If the Congress is serious about public health it must equip citizens with the tools to protect themselves when the bureaucracy fails to do so. It must also put real leverage behind legislated reregistration schedules, and it must shift the bias in the regulatory process - which now favors the industry - to favor public health.

Immediate Removal of 'Bad Actors'

It has now been fifteen years since the Congress first directed the EPA to reregister the nation's pesticides. Under current proposals - if enacted and adhered to - the job will take an additional ten years. Should the public be subjected to twenty-five years of poisoning before action is taken? It is time Congress shifted the burden of proof about the safety of these pesticides from the public to the manufacturers - and do so immediately in the case of those pesticides for which we have overwhelming evidence of danger. For the sake of public health, chemicals that have been in the reregistration program for 15 years should be removed from the marketplace until the manufacturer can provide adequate data to prove they are safe.

Congress should show the public, the EPA and the chemical industry that it is serious about public health by taking immediate action to suspend all uses of at least five pesticides that have been languishing in the bowels of the EPA far too long. Those five are:

Aldicarb - Produced by Union Carbide and marketed under the brand name Temik, this poison has been in EPA's special review process since July of 1984. Temik is one of the most acutely toxic pesticides in use today. Over two million pounds of Temik each year is applied to citrus fruits, potatoes, peanuts, bananas and a host of other food crops. Traces of Temik have been detected in groundwater in more than a dozen states. A study conducted by the Center for Disease Control suggests that Temik-contaminated water can cause immune system disorders in humans. According to EPA, Temik is highly toxic to mammals, birds, marine and freshwater organisms. Temik, a systemic pesticide that cannot be washed away down the kitchen sink, is many times more deadly to mammals than DDT. It is time to remove Temik from the market.

Alachlor - Better known as Lasso and produced by Monsanto, Alachlor is the largest selling pesticide in the U.S. Lasso is used widely on corn, soybean and other food crops. While Lasso is known to cause tumors in test animals, Monsanto has effectively escaped all regulation of its poison product. The EPA has found that drinking water that contains alachlor at levels of 10 parts per billion could cause as many as four cancers per 100,000 people. First marketed in 1969, under EPA's current regulatory pace, Lasso will remain on the shelves for at least two more years. Canada announced a ban on Lasso two years ago; Sweden banned Lasso in 1979.

Although studies as early as 1978 detected Lasso contamination in groundwater, and although EPA had data since the early 1980's showing Lasso's suspected oncogenicity, it was placed in special review only two years ago, some 16 years after it entered the marketplace. Why must we wait another two years, or another four years, or another six years to ban all uses of Lasso? If Monsanto cannot prove today that Lasso is not a health hazard, it should be ordered off the shelves.

Daminozide - Alar, the trade name for daminozide, is manufactured exclusively by Uniroyal and has been in our food chain for more than twenty years now. In 1986, approximately 850,000 pounds of this carcinogen was applied to our food crops, primarily apples and other fruits, to enhance their storage life and color. Alar has been lingering on the special review list since 1984. Alar's bi-product, UDMH, has been shown to be an even more potent carcinogen than Alar itself.

EPA initially proposed a ban on Alar in 1985, concluding that it was a "probable human carcinogen." The following year, however, EPA withdrew its proposed cancellation and instead ordered Uniroyal to conduct additional health studies. According to the Agency, the lifetime cancer risks from Alar are a stark one in 1,000 adults. EPA has calculated the risks to infants and children at level four to 15 times greater than adults. Massachusetts has taken steps to ban Alar from baby foods in the fall of 1987 and in most other heat-processed apple products by October, 1988.

Captan - An estimated 10 million pounds of captan are used annually in the U.S. to control fungus or disease on more than 80 fruit and vegetable crops, including apples, strawberries, peaches, carrots, corn, potatoes and lettuce. This fungicide is used at all levels of food production, from seed-treatment in corn and soybeans, to post-harvest treatments for potatoes and fruit.

Captan, an ingredient in approximately 600 commercial pesticide products, has been under special review at EPA since August, 1980, when it was suspected of causing cancer, mutagenic and other chronic health effects. According to EPA, Captan has since been proven to cause kidney tumors, intestinal tumors and birth defects in laboratory animals. EPA estimates the risk of developing cancer due to dietary exposure to captan at one case per 1,000 to 10,000 individuals, but it has yet to ban it, after seven years of study.

Chlordane - Chlordane is applied to approximately 1.5 million homes in the U.S. each year as a solution to termite infestation. This pesticide, classified by EPA as a "probable human carcinogen" of the chlorinated cyclodiene group of chemicals, has gained publicity because of its ability to permanently contaminate treated homes, as well as cause adverse health effects to homeowners.

Although chlordane was first registered in 1948, health and safety data gaps still exist for at least 18 areas of testing, including chlordane's effects on reproduction, its mutagenic ability and its potential to cause surface and groundwater contamination.

Humans living in affected structures can suffer chronic liver disorders, dizziness and blurred vision. Acutely toxic reactions to chlordane affect the central nervous system causing hyperexcitability, convulsions, depression and even death.

Though several states have taken action to ban the use of chlordane, we still have no final determination from EPA.

S. 1516, THE LEAHY-LUGAR BILL

Preemption of State Standards

The Leahy-Lugar bill, S. 1516, is an improvement over last year's House-passed bill (H.R. 2482) with regard to states' rights. Provisions to preempt the authority of states to set more stringent food residue standards for pesticides represent a serious disregard for public health. The support last year of such an amendment by the Grocery Manufacturers Association (GMA) and now the National Agricultural Chemicals Association (NACA) ought to be recognized as the power grab it really is.

Surely no one can seriously believe that the federal government's track record on pesticides, and especially pesticide residues in food, merits giving either EPA or FDA the last or only word in determining food safety guidlines in this country. For example, in 1984, states such as Florida had to adopt emergency guidelines to control the use of EDB while the federal government completed its seven-year review of the chemical. Today, daminozide is another example where states are moving ahead to protect public health while Washington lags behind. Occasional instances of action by the states demonstrate a regard for public health rather than an abuse of authority.

Given the prospect of federal preemption, it would be easy to imagine states taking less of an interest in monitoring intrastate food products, thus adding to the monitoring burdens of the FDA. And it is hard to imagine any situation where preemption would not be imposed by the federal government, if only to avoid the political problem of explaining why one state deserved greater protection than another.

Preemption of state standards would also set an undesirable precedent in environmental protection legislation. All major environmental statutes, including the Clean Water Act, the Safe Drinking Water Act, the Solid Waste Disposal Act, Superfund and the Clean Air Act, allow states to set more stringent standards if they choose. If FIFRA reauthorization includes a federal preemption provision in any form, it will invite similar demands by interest groups in subsequent reauthorizations of other environmental statutes.

Special Interest Immunity From Liability

Another special interest amendment in last year's House bill that contributed to its demise has again threatened to raise its head. I refer to the liability exemption for agricultural producers which is simply a bail-out for agribusiness disguised as protection for the small family farmer. Such a provision would serve as a disincentive for larger agricultural producers who might otherwise be more careful if they knew they could be liable for a clean-up action. All farm applicators would take more care than the label requires if they knew they might have to assume liability.

This amendment would also set another damaging precedent for environmental laws. In one stroke it would weaken Superfund, the Clean Water Act, the Solid Waste Disposal Act and Title XIV of the Public Health Service Act. Those laws in turn would be assaulted by a long line of special interest groups at the next reauthorization asking for "me too" liability exemptions.

Indemnification

The Leahy-Lugar bill takes a step forward by limiting the current practice of requiring EPA to indemnify chemical producers for their stocks of chemicals banned by the agency. However, any FIFRA reauthorization should take a second step by removing all burdens to taxpayers for having to pay producers to stop poisoning them. In no other federal law is the cost of regulation for environmental protection or public safety placed on the regulating agency. To quote John A. Moore, Assistant Administrator for Pesticides and Toxic Substances at EPA, "it is a ludicrous statutory mandate for this Agency to fund what is essentially an insurance program for registrants."

In response to questions from Senator Proxmire, Chairman of the Senate Appropriations Subcommittee on HUD-Independent Agencies, EPA recently gave some examples of the kind of indemnification costs it could face in the near future: alachlor, $161,500,000; linuron, $35,600,000; benomyl, $78,000,000; daminozide, $7,950,000; methyl bromide, $23,000,000; chlordane, $53,200,000; and dinoseb, $30 to $50,000,000. In the past the EPA has paid $18,000,000 for 2,4,5-T Silvex and $2,400,000 for EDB indemnity claims.

What is so special about pesticide producers that they deserve such a payoff? Do we pay the automobile manufacturer or the drug producer for the costs of a recall? The answer is no, and it is not warranted for pesticides. In fact, there is every reason to believe that the Agency may delay suspensions to avoid washing out its modest $60 million annual pesticide program budget. The Agency may also decide, as is rumored with the pending chlordane decision, to cancel the product but allow the use of existing inventories to reduce indemnification and disposal costs, notwithstanding the additional cancers that would be caused by such a policy. Producers with chemicals currently under special review have no incentive to stop making a product until a final cancellation takes effect because our government is required to pay for the harmful products whose dangers the manufacturers themselves should have tested for more throughly years ago.

Why should the pesticide industry be given a special invitation to come to the treasury and be reimbursed by the taxpayer for unrealized profits on their poisons? Haven't we eaten enough of these pesticides?

Exports of Banned Pesticides

Related to indemnification is the question of allowing suspended, cancelled and restricted products to be exported overseas where they are applied to food crops such as pineapples, mangoes and tangerines and imported back to America. The FDA monitors less than one percent of the one million import shipments for pesticide residues each year according to the GAO. The GAO, in two separate reports last year, found inadequate monitoring and enforcement of both imported and domestic foods for pesticide residues. With regard to imported food the GAO said, "FDA's pesticide monitoring program provides limited protection against public exposure to illegal residues in food." S. 1516 does not address this problem because it continues to allow these exports and fails to establish a comprehensive monitoring system to protect us from contaminated imported food.

Citizen Suits

The only major environmental statute without a citizen-suit provision is FIFRA. Neither the House nor Senate bills contained such a provision last year. Yet farmers, other individual citizens and states should be able to help enforce the law or use it to protect their safety and property. A provision similar to the citizen-suit mechanism in the Clean Water Act (Sec. 505) would allow citizens to sue the government or other violators to prevent imminent and substantial threats to health and property. Our sagging pesticide policy needs the help, and it would give industry an added incentive to comply, knowing there would be fewer cheaters to try to compete with.

Right-to-Know and Adequate Record Keeping

The community right-to-know program established under the 1986 amendments to Superfund will be invaluable to emergency personnel, firefighters, plant workers and community residents in the event of chemical accidents in years to come. However, some of the reporting required about chemical storage and emissions by storage facilities, transporters and large users will not always apply to pesticides. This will deny many rural communities the opportunity to prepare properly for accidents like the April 4, 1987 fire at a pesticide warehouse in Minot, North Dakota, which resulted in the evacuation of 10,000 people. The lack of reporting about pesticide use will also deny state and federal regulators valuable information needed to control future ground and surface water contamination.

A 30-year record keeping requirement should also be incorporated into FIFRA. This would foster more responsible behavior on the part of employers and allow for compensation to employees and better groundwater monitoring in the future. Because long-latency diseases, such as cancer, can be caused by pesticide exposure, it is essential that long-term records be kept. A similar concept was recently applied to EPA's regulations on asbestos-abatement activities.

Other right-to-know issues that relate to FIFRA include full disclosure of chronic health effects on the product label as well as the health effects not yet completely tested for as recommended by the GAO. This information should also include the listing of all inert ingredients in the product. EPA recently published a list of priority inerts, many of which are carcinogenic but are exempted from food tolerances. While the Agency and Congress consider the restriction of use of these chemicals, the public has a right to know which products contain them. One of these food use inerts is methylene chloride which the EPA recently banned as a propellant in hair sprays due to its cancer risk.

Require Health and Efficacy Studies

FIFRA reform legislation should also mandate certain studies, such as a periodic and comprehensive testing of mothers' milk for pesticide contamination. Recent studies by Colorado State University scientists found a staggering 90 percent incidence of DDE, a DDT metabolite, in the breast milk of humans. An earlier study by the same team in 1981 showed a 74 percent incidence of oxychlordane and other pesticides in human breast milk. Oxychlordane is a metabolite of chlordane.

Under the current FIFRA statute, the Administrator can waive requirements that the pesticide registrant provide evidence of a product's efficacy. According to the U.S. Department of Agriculture, in 1965, 185 species of insects were resistant to one or more pesticides. By 1984, 447 species had acquired similar tolerances. I would like to submit for the record an article from the March 21, 1987 edition of The Economist regarding the increasing rate at which insects are building immunities to pesticides. The evidence suggests we are dumping greater amounts of poison into the environment while gaining fewer of the desired effects. The EPA should be mandated to undertake a detailed study of the efficacy of pesticides now on the market. Efficacy studies should also be required by EPA, with no waiver provisions, of all pesticide registrants.

Patent Term Restoration

The linkage of patent term extension legislation with pesticide reform was key to the negotiated compromise bill of last year. Any legislation with such a windfall to the chemical industry should yield a substantial gain in the area of public health protection. Patent term extension should not be granted if the FIFRA reauthorization package includes federal preemption or special liability exemptions and does not include citizen enforcement tools and mechanisms that require removing inadequatly tested pesticides from the market if deadlines are not met.

Thank you for the opportunity to testify today. I urge you to enact pesticide legislation during this Congress that finally puts public health before corporate wealth.

SCIENCE AND TECHNOLOGY

How bugs and pests rout the chemists

BOSTON

The ingenuity of chemists is no match for the versatility of evolution. In the battle against plagues and pests, the enemy has for some time deployed a strategic defence initiative: resistance. Bacteria are evolving resistance to antibiotics and insects resistance to pesticides faster than new chemicals are being invented. Before long, at this rate, medicine will revert to the days before penicillin, and agriculture to the days before DDT. Little prospect of relief is in sight. Ways exist to avoid resistance but chemical companies, doctors and farmers have no incentive to adopt them.

Resistance is one of the clearest instances of Darwinian natural selection. As soon as penicillin is injected into your body, an advantage accrues to any rare bacterium that happens to possess a way of disarming the chemical. It survives while the others perish. Resistance then spreads from bug to bug because most of the resistance genes lodge themselves in plasmids: small loops of DNA that bacteria swap with each other. Resistance is usually irreversible. It can also move between species of bacteria: a harmless soil organism made resistant by antibiotics on a farm can pass the resistant plasmid to a strain of *Salmonella*. In the United States, half of all antibiotics are used to make farm animals grow faster.

Again for Darwinian reasons, the enemy gets better at developing resistance: selection encourages the quick evolvers. Five successive generations of pesticides have passed since DDT was first used in the 1940s. The time it takes for the number of species of insects resistant to each new generation to double has fallen from 6.3 years for DDT to one year for the newest generation of pesticides, pyrethroids. Colorado potato beetles have beaten almost everything thrown at them. In the beginning, it took them many years; today, they can beat a new insecticide in a season. Meanwhile, many of the insects that eat Colorado beetles are still susceptible. Spraying simply encourages the beetles: they are, says Dr Robert Metcalf of the University of Illinois at Champaign-Urbana, out of control.

More than 450 species of insect are now resistant to DDT. The most famous is the mosquito, which turned the World Health Organisation's 21-year, $2 billion campaign to stamp out malaria into a rout. For example, in 1963, the programme had worked so well that there were only 17 cases of malaria in Sri Lanka. But that year resistance appeared. By 1968, the country had an epidemic of more than 1m cases.

Antibiotic resistance has yet to produce such a medical disaster but it will do so before long. Dr Stuart Levy of Tufts University has found that more than half the benign bacteria in human guts in Massachusetts are resistant to at least one antibiotic. Benign bacteria can pass on resistance to harmful ones. In the United States, the first case of penicillin-resistant gonorrhea appeared in 1976; by 1985, 8,500 cases were reported.

Multiple resistance is a new worry. Dr Levy has done experiments raising chickens on tetracycline. Within 12 weeks, their gut bacteria were resistant not only to tetracycline, but to several other antibiotics as well. In Tanzania, cholera has evolved resistance to several drugs, though only one was used. The same is happening among insects. In 1976, only seven species were resistant to all five classes of insecticide; now, 17 are, including house-flies, cockroaches and mosquitoes.

Nor is genetic engineering yet much of a help. The first genetically-engineered crops will have genes conferring resistance to herbicides (so that farmers can spray more herbicide on nearby weeds), and resistance to insects conferred by a gene taken from bacteria. Both will simply encourage resistant weeds and bugs to appear quicker.

Cost-ineffective

At the same time the chemists are stumbling. The number of new kinds of pesticides and antibiotics invented each year has fallen fast over the past quarter-century. Between 1980 and 1985, no new pesticides were introduced at all. Meanwhile, costs have climbed relentlessly. Synthetic pyrethroids cost 100 times as much in real terms to develop as did DDT (and the best of them, deltamethrin, 1,300 times as much). The ever more rapid appearance of resistance has put chemical companies in a squeeze. They have less time in which to recoup greater costs, so they encourage wider use, which accelerates the appearance of resistance.

What can be done? The chemical industry may find a way out of its dilemma by developing chemicals that fight resistance. For example, Dr Samuel Martin and his colleagues at the Walter Reed Army Medical Centre in Washington, DC have recently shown that they can reverse resistance in malarial parasites to chloroquine, an antimalarial pill. They did so by learning from cancer cells, which can also develop resistance to drugs. Cancer cells achieve resistance by becoming more efficient at getting rid of the drug and so preventing it accumulating: hence, the cell can resist various kinds of drug after being exposed to only one.

A chemical called verapamil fights this excretion and so reverses resistance. In the laboratory, it also works for chloroquine-resistant malaria. Perhaps, one day, it will be possible to give people penicillin together with a chemical that reverses resistance to penicillin.

Such ideas are futuristic. At the moment, the only answer for both pesticides and antibiotics is to use them sparingly. This not only postpones the spread of resistance, but in some cases can head it off altogether. Antibiotics, Dr Levy says, should not be used in farms, not be used indiscriminately for weeks before surgery, and should not be available over the counter for all sorts of unsuitable ailments, as they are in many poor countries. In Mexico, scientists have found that the amount of resistance correlates neatly with the availability of antibiotics.

Similarly, insecticides, used carefully, need not produce resistance. In Australia, it is illegal to use synthetic pyrethroids on *Heliothis*, a cotton pest, except during a 40-day period each year when the bug is most vulnerable. After five years of prohibition, no evidence of resistance to synthetic pyrethroids has appeared in Australia. In the rest of the world, cotton growers profligate in their use of the stuff have had no trouble producing resistance.

In another case, Dr Brian Croft of Oregon State University has persuaded the chemical industry to leave off its label any suggestion that pyrethroids be used in summer against a pest called *Psylla*. Again, resistance has been avoided. In Italy and East Europe, which have used the pesticide in summer, resistance is rife.

Such practices are hard to introduce. No farmer likes to watch a pest developing when he knows he can kill it, and no salesman wants to tell him to use the stuff sparingly. Dr Croft admits that some of the best successes owe more to serendipity than to good management. The codling moth, for instance, is not (so far) resistant, while the insects that eat it are. That is pure luck.

Farming will survive—it can breed plants in the right rather than the wrong direction (see box)—but human health will suffer. The only hope is that genetic engineering can deliver weapons that evolve as fast as the enemy. That is not as far-fetched as it sounds: several insects are already fought by spraying them with viruses that give them diseases, and there is talk of doing the same for bacteria. Viruses can out-evolve bacteria, chemists cannot.

Senator **Fowler**. Thank you, Mr. Nader. I did not know of the volume number amount. Your point is that taxpayers are paying twice, they pay for printing, and they have to buy it in the store if they want it.

Mr. **Nader**. Yes, from the GPO. If you want to print more than 300 then you have to have the special acknowledgement to print more than 300.

Senator **Fowler**. When did that come into effect? I mean is that because of our budget cutting?

Mr. **Nader**. Yes.

Senator **Fowler**. Is that the announced reason for the cutback?

Mr. **Nader**. That is the announced reason in contrast to the congressional salary increases in recent years.

Senator **Fowler**. Well, you have gone from preaching to meddling now. [Laughter.]

Mr. **Nader**. You know it went even further. There was a proposal that was finally jettisoned by Senator Mathias and his House counterpart to require people to pay for congressional bills and congressional reports right from the outset, and that was last year. And they dropped it. Now they have a limitation. I guess it is directed against some of the trade associations and law firms who order a lot of copies. I think we really have to pay much more attention to these things.

The Congressional Record now is over $225. When I was in college it was $12 a year. Keeping up with inflation would bring it to about $40 a year. It is just priced out of the hands of most people.

Senator **Fowler**. Well, if we had an efficacy test on the comments in the Congressional Record, too, we would severely limit anybody's interest in it.

Mr. Nader, let me ask you this. On your listing of the five pesticides, I noted that you mentioned, and in your testimony, you believe that EPA should cancel. Would not the passage of our bill S. 1516 help accomplish a result? I assume you are not advocating not providing due process to the registrants of these pesticides?

Mr. **Nader**. Well, under the proposed legislation, if they are all enacted and adhered to, the job of reregistration will take about another 10 years instead of another 20 or 30 years, but the process has been under way now for 15 years, and I think Congress can make a finding, based on the evidence that the EPA has brought together, that the time is up.

Bill of attainders only apply to protect human beings.

Senator **Fowler**. This bill is—again, I know that I am not talking to an incrementalist, and I do not like the incremental nature of many of our painful steps when faced with obvious difficulties in many areas of public policy. But I do want you to—it would be helpful. This bill is an improvement, in your opinion, over the not only current law, but also the House bill's approach, is it not?

Mr. **Nader**. In a peculiar way. Yes, it is better than the House bill.

Senator **Fowler**. Well, I knew I was not going to be able to say it my way. Describe its peculiarities.

Mr. **Nader**. Yes. First of all, I guess I could be accused of being an incrementalist for the last 15 years, as we all can. There has to be some statute of limitation on incrementalism before it becomes institutionalized as a clear and present danger to the American people, this incredible delay and inaction.

But let us say you have a river that you have to cross, Senator, and it is a small river, and the flood is coming. And every 30 minutes that river expands so it is more difficult to ford. And someone says to you I am going to take you across that river safely, and they take you from the bank down to the edges of the rushing waters, and then they stop. And you say, well, take me across the river safely.

And the person says to you, "what do you want from me? I have gotten you closer than before, have I not?" It will not work. Without citizen suits, without the ending of indemnification, without right-to-know, without health and efficacy studies, and these other points that I made, you may have a textural improvement, but you are not going to have very much of a withdrawal improvement in terms of the dangerous pesticides.

The export provision is a perfect example of that, Senator Fowler. It is an improvement texturally over what is going on now in terms of export of banned pesticides, and it involves notifying the receiving company in the country and notifying the regulator in the country and working with other countries.

Senator **Fowler**. Well, how should we do it? As you probably know, this committee does not have jurisdiction over FDA, but I am not offering that as an excuse, but what should our policies be? How specifically should we handle our export monitoring?

Mr. **Nader**. The policy is simple. What is safe for the American people is what is safe for foreign citizens. What is unsafe for the American people should be unsafe for the foreign people.

Senator **Fowler**. At any speed?

Mr. **Nader**. Yes. [Laughter.]

I do not think that a Brazilian liver is any more resistant to some of these pesticides than an American liver.

Senator **Fowler**. Well, you are going to get some debate from the Brazilians if you have ever eaten some of their meals.

Mr. **Nader**. You think they may have developed an immunity?

Senator **Fowler**. That is right.

Mr. **Nader**. They do not mutate that fast. I think a parity of safety enhances the respect that the rest of the world will give us, too. You know that "made in USA" label should have a reputation attached to it. And it should not be a made in USA, dangerous for Americans, but it is okay for you Mexicans and Brazilians and Nigerians. Same with drugs, I might add, pharmaceuticals.

Senator **Fowler**. Do you believe there is urine in Corona Extra beer?

Mr. **Nader**. I do not know anything about that.

Senator **Fowler**. The front page of the business section today. Poor Mexicans. Just as they were selling all their beer, the yuppies are now being told there is an added elixir that is not an aphrodisiac.

Mr. Nader, I thank you for your very helpful testimony. I do think just like a national energy policy, and let me end by saying that we ought to have a policy. We certainly ought to have a national policy. And our sometimes feeble efforts, halting though they may be, are not fast enough or firm enough in many of these areas.

This is once again a long overdue approach, but your suggestions are specific and clear, and very helpful.

Mr. **Nader**. Thank you, Mr. Chairman.

Senator **Fowler**. Thank you for your testimony. We thank everybody. The committee will resume these hearings at 2:00 this afternoon.

[Whereupon, at 12:25 p.m., the committee recessed, to reconvene at 2:00 p.m., this same day.]

AFTERNOON SESSION

Senator **Harkin** [presiding]. The committee will come to order. First of all, I would just like to apologize to all of you for being late, and especially to my esteemed colleague, Senator Lugar. I know your time is very valuable, and I apologize for holding you up here.

Our panel this afternoon is Jack Early, president, National Agricultural Chemicals Association; John Hagaman, president, Global Agricultural Products, the Dow Chemical Co.; Dr. Warren Stickle, executive director of the Chemical Producers and Distributors Association; Robert Shockey, president of the Chemical Producers and Distributors Association and chairman of the board of Drexel Chemical Compounds, Memphis, Tennessee; Dennis Burchett, vice president, regulatory affairs, United Agri Products, the agriculture chemical division of ConAgra; and Ralph Engel, president of the Chemical Specialties Manufacturers Association. We welcome you all to the Senate Agriculture Committee. We will just go down the line as I introduced each of you, and I am notified that you each have 5 minutes per person, and I apologize for that, but I guess that is the time constraints we are under.

Mr. Early, without further ado, please proceed. If you have a prepared statement, and I see that you do, it will be made a part of the record. If you would just like to go ahead and summarize it, I would be most appreciative.

STATEMENT OF JACK D. EARLY, PRESIDENT, ACCOMPANIED BY SCOTT FERGUSON, GENERAL COUNSEL AND VICE PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, DC

Mr. **Early**. Thank you, Mr. Harkin. I do have a prepared statement for the record, and I appreciate submitting it as it is.

I wish to thank you and the committee and the chairman for the opportunity to participate in this hearing on FIFRA amendments.

While we recognize that the work that the committee and the staff have done on this bill, we must tell you at the outset, we are opposed to S. 1516.

The reason is simply that S. 1516 is a weaker bill than passed by the Senate last year. It omits or modifies provisions that are critical to the interest of agriculture, the environment and the public. These modifications and omissions are: deletion of an ambitious but balanced title on ground water protection, deletion of modest tolerance uniformity provisions, deletion of a farmer liability compromise, modification of longstanding indemnification for agriculture, and imposition of excessive reregistration fees.

In my remaining time, Mr. Chairman, I wish to speak briefly to several of these issues. Mr. Hagaman will speak separately on certain business issues.

Turning now to the first major omission, a ground water protection provision. Last year we worked with all interested parties to formulate a Senate ground water provision. Despite our best efforts, the Senate's ground water provision was overly complex, ambiguous, and inadequate in protecting agriculture and the environment. Many of those same deficiencies—and more—exist in the recently introduced S. 1419.

We believe that the version currently before the House of Representatives, H.R. 2463, which passed that body three times last year is preferable. I might add it passed one time on unanimous consent.

My second point, Mr. Chairman, relates to the modification of current indemnity provision in FIFRA. We believe that the change from assured to uncertain indemnification through congressional appropriation will ultimately be bad for agriculture. As supported in my extended remarks, my reason for those are fairness and economics. Again, we prefer the approach in H.R. 2463.

My third and final point on S. 1516 is regarding uniform tolerances and farmer liability. We are certain that members of the agricultural community will speak to the importance of these provisions in their continued support for FIFRA amendments. Failure by Congress to address these matters will be a significant oversight.

In conclusion, Mr. Chairman, I wish only to reemphasize what is obvious to all of us: that the time available for Congress to deal with the issues raised in S. 1516 is rapidly waning. We hope that this committee will be able to conclude the positive efforts made last year and that are still possible today. Thank you, Mr. Chairman. Mr. Hagaman has a statement.

[The prepared statement of Mr. Early follows:]

TESTIMONY BY DR. JACK D. EARLY,

PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Before the

Senate Comittee on Agriculture, Nutrition and Forestry

July 30, 1987

Mr. Chairman, I wish to thank you and the Committee for the opportunity to participate in this hearing on FIFRA amendments.

As you know, together with a coalition of over 40 environmental groups, NACA worked cooperatively with its friends in agriculture and this Committee to hammer out major changes to FIFRA last year. We did this, not because we and others saw a crisis that needed a Congressional response, but in an honest effort to resolve, through compromise, a number of seemingly insolvable differences with the mainstream of environmentalists on the operation of FIFRA and to foster product innovation that will benefit agriculture into the next century.

Our desire to meet these twin objectives has not diminished and we stand ready to support a bill that will accomplish these objectives. S.1516 is not that bill.

S.1516 is a weaker bill than passed the Senate last year. It omits or modifies provisions that are critical to the interests of agriculture, the environment and the public--and ultimately to allowing support for S.1516. These modifications and omissions are: deletion of an ambitious but balanced title on ground water protection, deletion of modest tolerance uniformity provisions, deletion of a farmer liability compromise, modification of long-standing indemnification for agriculture, and imposition of excessive reregistration fees.

In my remaining time, I wish to speak briefly to several of these issues. I request that my extended remarks be included in the record. Because of their special importance, Mr. Hagaman will also speak separately on certain business issues.

Turning now to the first major omission, a ground water protection provision. Last year we worked with your personal staff, the staffs of the Senate Agriculture Committee and the Environment Committee, the environmental coalition, grower groups, EPA, and many others to help formulate a ground water provision for the Senate bill. Despite our best efforts, the Senate's ground water provision was overly complex, ambiguous, and inadequate in protecting agriculture and the environment. Many of those same deficiencies--and more--exist in the recently introduced S.1419, which I address separately in my extended comments. For example, S.1419 contains an unrealistic ground water definition, unenforceable goals for water quality standards, and unworkable state ground and surface water protection program. We believe that the version currently before the House of Representatives, H.R.2463, which passed that body three times last year, is preferable to any past and current proposals on ground water before the Senate.

My second point relates to the modification of current indemnity provisions in FIFRA. We believe that the change from assured to uncertain indemnification through Congressional appropriation will ultimately be bad for agriculture. As supported in my extended remarks, there are four reasons for this conclusion. First, there is no guarantee that agricultural users will recoup their losses, either from Congress or their suppliers. Second, financially threatened owners may use or sell suspended products, thereby frustrating efforts to protect health and the environment. Third, the seasonal business of agriculture that requires us to maintain the risk of huge inventories, together with uncertain indemnification upon product suspension, will chill interest in the agrichemical business and investing in new products. Fourth, EPA data requirements, registration and continuing oversight of pesticides make EPA a partner with registrants and users in sustaining a small part of the losses, if, through no fault of anyone, a product must be suspended and cancelled.

My third and final point on S.1516 is with respect to two titles deleted from last year's bill: uniform tolerances and farmer liability. We are certain that members of the agricultural community will speak to the importance of these provisions in their continued support of FIFRA amendments. We will not comment on the merits of those provisions apart from saying that agriculture's important initial and continuing support of FIFRA amendments last year was in large measure due to the prospect of correcting what some saw as troublesome problems in these two areas. Failure by Congress to address these matters would be a significant oversight.

In conclusion, Mr. Chairman, I wish only to reemphasize what is obvious to us all, that the time available for Congress to deal with the issues raised in S.1516 and alternative amendments is rapidly waning. We are interested in seeing changes to FIFRA along the lines of those considered last year, but are alarmed that continued delay will make this impossible for the foreseeable future. We sincerely hope that those special interests that wish to squeeze out or retract one more concession will not deflect this Committee from concluding the positive efforts made last year and are still possible.

Thank you, Mr. Chairman. I look forward to working with you and this Committee in the coming weeks and thank you again for allowing me to participate this afternoon. In the remainder of my testimony I will address in detail a number of issues raised in S.1516.

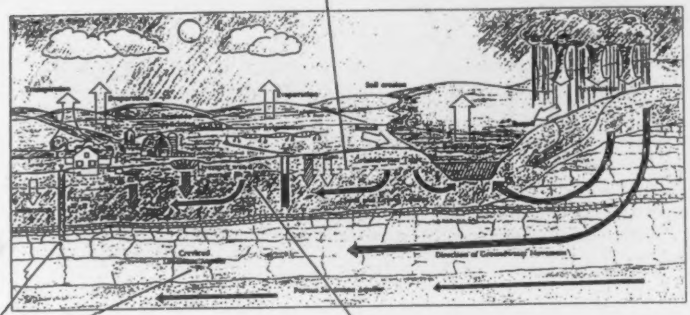
GROUND WATER

Mr. Chairman, I would like to turn my attention now to S.1419, the Ground Water Safety Act of 1987. I will begin with some general comments about this bill and then illustrate my points with some comments about specific provisions.

NACA supports enactment of legislation to identify pesticides that have the potential for leaching through the soil, to prevent contamination of ground water, and to respond to contamination when it occurs. In fact, after a great deal of effort, industry reached agreement with representatives of the environmental community last year on ground water provisions in the FIFRA reauthorization bill. Those provisions are reflected in the bill under consideration in the House, H.R.2463. We are prepared to stand by that agreement. It represents a tough new approach to ground water protection. At the same time, it is a bill that can be implemented. It is a bill that will be effective because, unlike S.1419, it focuses resources and efforts on real problems.

S.1419, however, falls far short of last year's bill in several key respects, which I will describe in a moment. The result is a bill with some very troublesome provisions, provisions that would harm American agriculture in return for little or no environmental gain. I will mention a few of these provisions.

One of the most important aspects of a law that is intended to protect a public resource is to define the resource that is to be protected. S.1419 does this by defining the term "underground source of drinking water." It is reasonable to expect that the definition of this term would, in fact, include ground water that is a present or potential source of drinking water; however, this is not the case. The bill uses such a broad definition of "underground source of drinking water" that it would include ground water which is likely never to be used for drinking. It would force stringent regulation of pesticides to protect ground water that is unfit or unavailable for drinking for reasons entirely unrelated to pesticides. I have illustrated this point in the figure below.



S.1419 requires all ground water below this line to meet or exceed drinking water quality. Note that this includes water near septics, storage, surface, and other areas never used for drinking water. S.1419 hurts agriculture.

H.R.2463 requires current and potential drinking water to meet drinking water standards. Pesticides that cause unreasonable adverse effects in other ground water are prohibited. H.R.2463 protects both agriculture and ground water.

Let me explain why the definition in S.1419 does not make sense. The definition in S.1419 says that an aquifer is a potential source of drinking water if it contains enough water to supply a single well or spring and is not too salty or too brackish to drink. Common sense would suggest that there are other factors that should be considered, factors such as the presence of other contaminants, anticipated future drinking water needs in the area, depth, geographical location, alternative sources of ground water, hydrogeologic factors, and aspects of water quality other than brackishness or hardness. S.1419, however, does not allow consideration of these factors. The bill is inflexible on this point. Let me illustrate this problem with two examples of aquifers that would be included by the definition in S.1419.

The first example is a hydrocarbon-bearing aquifer, really an oil-bearing stratum that also contains some water. No matter how oily the water, no matter how useless as a water supply, S.1419 would consider it to be a source of drinking water.

The second example is a more common one. In much of this country, there is a shallow freshwater aquifer that is only a few feet below the surface. Because it is so shallow, it easily becomes contaminated by activities taking place on the surface. In such a shallow aquifer, you may find nitrates from fertilizer application and feedlot drainage, roadway de-icing salts, pollutants from septic tank drainage fields, industrial wastes from sumps and lagoons, and many other contaminants besides pesticides. Water supply wells usually tap deeper aquifers, in part because they are less likely to be contaminated and in part because they often yield a better flow because there is a larger hydraulic head. S.1419 would consider an aquifer that already is contaminated with a host of pollutants to be a source of drinking water, to be protected at all costs against the addition of even inconsequential amounts of pesticides. Even if regulatory officials agreed that it makes no sense to do so, S.1419 would require them to impose the same regulations on these aquifers as for others that are legitimate drinking water supplies.

To put it directly: this one definition in S.1419 establishes a mandatory, universal non-degradation policy for nearly all ground water. It does so by defining virtually all underground water to be a source of drinking water.

The bill to which industry and environmentalists agreed last year took a different approach. It had a separate definition of "potential source of drinking water," and it defined that term fairly. It recognized that some aquifers are not, in any reasonable sense, a potential source of drinking water. It accomplished this in a straightforward way; it simply allowed consideration of such factors as the quantity and quality of water in the aquifer; hydrogeologic variables; depth; geography; and criteria and guidelines for purity of water established under the Safe Drinking Water Act and state guidelines. This language is incorporated in H.R.2463.

In introducing S.1419, Senator Durenberger justified his new and expansive definition by saying that it was taken from the Underground Injection Control (UIC) program of the Safe Drinking Water Act. That statement is accurate, but he failed to note that the program has a procedure for exempting some aquifers from this broad definition. Aquifers may be exempted because they are hydrocarbon- or mineral-bearing, on the basis of their quality or location, or for other reasons. In other words, the UIC program starts with a broad definition, then provides for exemptions where it does not make sense to include a particular aquifer. Several states, including Montana and South Dakota, have exempted aquifers from the hazardous waste injection control program. It is the exemption provision that makes the definition workable in the Safe Drinking Water Act because it introduces the necessary flexibility. S.1419 uses the same definition, but it lacks the flexibility to allow even the smallest exemption.

This definition is important because it ties in so closely with the regulatory standards and triggers elsewhere in the bill. I will turn now to a discussion of these provisions.

S.1419 would trigger various kinds of monitoring and regulation when a pesticide in ground water reaches a fraction of its "Groundwater Residue Guidance Level" or GRGL. For many pesticides, the GRGL must be equal to the Maximum Contaminant

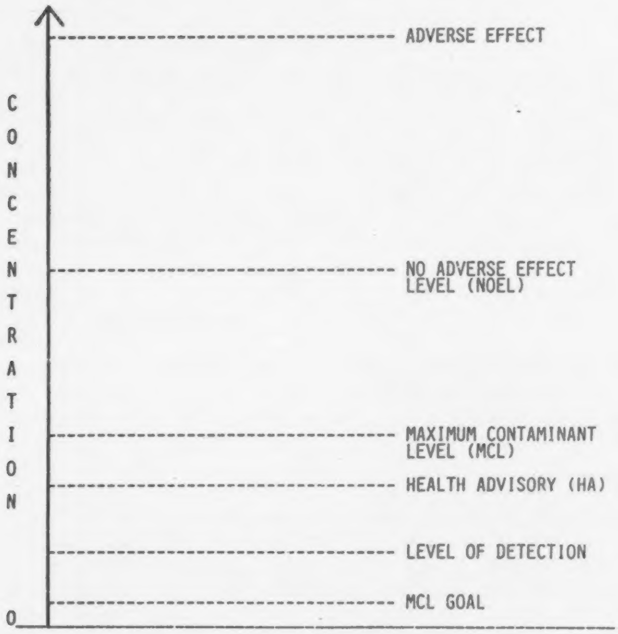
Level Goal (MCLG) established under the Safe Drinking Water Act. The MCLG is a non-enforceable, ideal goal. To establish an MCLG, EPA first determines the level of concentration of the substance that would lead to no adverse health effects. Then, just to be sure, EPA reduces this number by a large safety factor, usually 500. Thus, the MCLG represents a concentration level that is perhaps 100-to-500-fold or more diluted than the "no-effect" level. It is important to note that no technological or economic considerations go into the determination of an MCLG. It is purely a theoretical calculation that leads to a non-enforceable, ideal goal.

EPA calculates a Maximum Contaminant Level (MCL). Economic and technological considerations affect the MCL, and it, not the MCLG, represents that enforceable standard of purity for public drinking water. These are the standards of purity for water supplies in virtually every U.S. city and town. These concepts are illustrated in the figure below.

o BOTH BILLS ADOPT A HEALTH BASED STANDARD (GRGL) FOR PROTECTION, BUT:

-- H.R.2463 USES THE MAXIMUM CONTAMINANT LEVEL

-- S.1419 USES THE MCL GOAL.


ADVERSE EFFECT
CONCENTRATION
NO ADVERSE EFFECT LEVEL (NOEL)
MAXIMUM CONTAMINANT LEVEL (MCL)
HEALTH ADVISORY (HA)
LEVEL OF DETECTION
MCL GOAL
0

S.1419 uses the MCLG, not the MCL, as the basis for regulation. S.1419 thus takes a non-enforceable goal established under the Safe Drinking Water Act and causes it to be used under FIFRA to support regulatory actions. H.R.2463, on the other hand, ties the GRGL to the Safe Drinking Water Act MCL, which is an enforceable standard that has been subjected to rulemaking procedures.

The use of the MCLG rather than the MCL in S.1419 creates an anomalous imbalance in regulatory standards for drinking water quality. Water still in the ground in Kansas or Iowa often would be held to a higher standard of purity than drinking water delivered to consumers in Chicago or Denver.

Having converted the Maximum Contaminant Level Goal into an enforceable standard, S.1419 then triggers regulatory actions on the basis of a pesticide being detected in ground water at a fraction of this standard. For example, if EPA determines that a pesticide is present in an underground source of drinking water at a concentration that is 50% of the GRGL, the state is required to take emergency action to ban or otherwise restrict the sale or use of the pesticide. If the state fails to take this action, EPA is required to ban the use of the pesticide in the vicinity of the source, to order the registrant to provide an alternative water supply, to initiate civil or criminal actions, or to seek other relief.

This is the point to recall the extremely inclusive definition of "underground source of drinking water" in S.1419 and consider it in the context of these regulatory requirements. Imagine a shallow aquifer that is already contaminated by natural conditions, a septic field, or fertilizer applications. Imagine that it lies in an area where there is abundant surface water or deeper aquifers that may be used for drinking water. Now imagine that a pesticide is detected in this shallow aquifer at a level that is less than 1/1000 of the level that scientists have decided is a "no-effect" level. Does it make sense to lay down a rigid and inflexible requirement that the already contaminated water must exceed drinking water standards and the pesticide must be subjected to use prohibitions throughout the area? Should this be done without even considering what effect that would have on the ability of farmers to produce a quality crop and make a decent living? That is what S.1419 does, and I would submit to this Committee that it simply does not make sense.

What does make sense is to start with a reasonable definition of the resource that is to be protected and allow some measure of flexibility to account for the diversity that is in the real world. Then use a regulatory standard, such as the Safe Drinking Water Act MCL, that has had public participation in its development and is intended to be enforceable. Then reserve the toughest types of regulatory actions, such as use prohibitions, for situations in which current drinking water wells are threatened. If you agree with me that this makes sense, then I would urge you to examine very closely the provisions that were developed last year by the industry/environmental coalition, because the conceptual framework I have just described is taken from that agreement. It is reflected in H.R.2463.

I would like to describe one more aspect of S.1419 that, in many ways, is the most troubling of all. I am referring to the requirement for the establishment of state programs to prevent water pollution. At first glance, this would appear to be a provision that is hard to oppose. Who could quarrel with the idea that states should establish such programs? Our problem arises because of the need to create a whole new bureaucratic organization and the consequences to agriculture if either the state or EPA drops the ball. The bill would require states to establish regulatory programs that meet certain vague criteria. These programs would not go into effect, however, until EPA has reviewed and approved them. We know from experience that it is likely to be many years before all states would have an approved program in place. However, S.1419 would automatically prohibit use of certain pesticides in a state if the state does not have an approved program within three years.

There are any number of reasons why a state might not have an approved program within this time frame. It may take EPA a while to publish the necessary regulations. Perhaps a particular state agency needs new statutory authority. Some legislatures meet only once every other year, and even then there is no guarantee the necessary bill would pass. Perhaps program development is delayed because of lack of resources or because of bickering between competing agencies. Even if, by some miracle, a state is able to make a timely submission to EPA, how quickly can EPA review and approve fifty state program submissions? What is to prevent arbitrary EPA denial of a state plan? S.1419 does not allow any of these factors to be considered. If the program is not approved within three years, the pesticide cannot be used in the state. It does not matter whether this would result in loss of major crops or the bankrupting of half the farmers in the state. The bill is clear, and there is no effective relief. The only way to stop these results is for EPA to determine that the pesticide is not capable of leaching through the soil or occurring in surface water run-off. This is not likely to help much because the bill requires immediate cancellation of the pesticide in the state if it is detected thereafter even one time at any level in any sample of any surface water or ground water.

I am sure the Committee can see that this provision could force important pesticides off the market due to bureaucratic failures alone, without regard to whether a risk is actually present, economic importance of the pesticide to farmers, or need for the crop involved. This provision is fundamentally unfair to farmers and pesticide manufacturers alike because it would penalize them for actions over which they have no control. The quantity and quality of a crop in an entire state could be damaged because of inadequate agency staffing, foot dragging, or any other factors that contribute to a state's failure to create a new regulatory bureaucracy and get it approved by EPA within the prescribed time frame.

Mr. Chairman and Members of the Committee, I have taken the time to point out to you only the most serious problems with this bill. There are a number of other provisions that do not stand up to scrutiny as well, but my purpose in these comments is simply to urge you to take the time for a close look. S.1419 is not a bill that would be a credit to this Committee or the Senate. By failing to allow common-sense distinctions between those aquifers that are potentially useful as a source of drinking water and those that never will be used for that purpose, drastic action would be required to solve "problems" that are not real, while those that are real would fail to receive appropriate attention. Such rigid and inflexible requirements could cause immense harm to the agricultural economy.

What S.1419 seems to ignore is the value of pesticides to the agricultural economy. Before endorsing a bill that so casually would deny farmers the use of pesticides, I would urge Committee Members to consider these facts:

- o Pesticides provide a strategic resource in the battle to control pests that will otherwise cause widespread and economically significant damage to almost all crops grown in the United States. Pesticides lead to increased availability of commodities, lower prices for commodities, and improved quality of commodities, especially fruits and vegetables.

- o The benefits of pesticide use are derived directly from the control of insects, nematodes, weeds, rodents, and plant pathogens afforded by the use of a variety of pesticidal agents. In the pest management context, insecticides are the only practical control measure for insect pest populations approaching or at infestation levels that will cause economic damage. They have rapid curative action in preventing economic damage, offer a wide range of properties, uses, and methods of application to pest situations, are low in cost, and are associated with substantial financial returns to growers.

- o Stopping the use of pesticides, it has been estimated, would result in a 9% to 50% decrease in crop production. A 9% decrease would be associated with an $8.7 billion increase in crop losses and a 12% increase in the retail price of commodities. A 50% decrease has been estimated to cause up to a 400% to 500% increase in retail food prices.

These average statistics, as compelling as they might be, mask the potentially devastating regional and individual crop impacts due to the loss of chemical pesticide control. In many areas and on many crops, pesticides are the only means to control pests whose presence would otherwise prohibit production of certain crops. Without pesticides, crops such as apples and most tender fruits and many vegetables, including onions and cole crops, would not be available in quantity, and the price would be excessively high. Yields per acre in cereals and corn would be drastically reduced.

Mr. Chairman and Members of the Committee, I hope these comments have persuaded you that S.1419 contains provisions that, perhaps, have not been fully thought out. By contrast, the ground water provision that appears in H.R.2463 is the product of months of research and discussion by industry and environmentalists alike. I urge the Committee not to discard that effort.

DATA COMPENSATION

I would like now Mr. Chairman, to turn to another vital issue: data compensation. Data compensation refers to the amount of money one company must pay another for the use of its research and test data. When a non-research firm wishes to manufacture a product developed by a research firm, it must provide test data to EPA. It has three options in this regard: 1) it can develop the data itself, as the research company did; 2) it can use the research company's data; or 3) it can wait until the compensation period expires, and then use the research company's data. Data compensation becomes an issue only if the non-research company decides to use the research company's data but not wait. If the non-research company does not use the data until after the compensation period expires, it gets the data absolutely free, and pays no compensation whatever.

The current law provides that the two companies should try to settle data compensation through private negotiations. If they cannot agree, the non-research company may still use the data and sell the product, and the question of fair compensation is submitted to impartial arbitration. Arbitrators from the Federal Mediation and Conciliation Service are appointed, and the parties make their case.

It is important to point out that non-research companies need not pay any compensation to enter the market. They must only promise to pay. Therefore, companies can be on the market, competing with companies who did the studies, while negotiation or arbitration is underway. For example, there are several non-research company products which have been on the market for several years. Each is relying on data developed by a research company, but the registrants have so far paid nothing for the data.

As a practical matter, most cases are settled. To date, there has been only one case which has gone through arbitration. In that case, the non-research company was required to pay an amount that is less than it would have cost to develop the data itself. Therefore, it benefitted by having the option of using data compensation. That company is on the market selling the product, and is not lobbying Congress today for a change to FIFRA. However, other non-research companies are. They want to abolish the impartial arbitration system in current law. They apparently are unwilling to make their case to an impartial arbitrator and are trying to use political muscle to get their way.

Compromise language on data compensation was adopted by this Committee in the 99th Congress by a 15-1 vote that makes the arbitration decision non-binding on the non-research company. Further compromises were made by the House Committee that were incorporated into S.1516. In other words, the Senate language says that, if the non-research company did not like the decision, it could "walk away" from it with no further obligations. The research company would not have this option--the arbitration award would always be binding on it.

We believe the data compensation provisions in S.1516 are fair and equitable to all concerned and should be approved once again by the Committee. Painstaking and expensive research is necessary to develop the very few products that possess the unique characteristics required of successful pest control, i.e., the ability to selectively control pests without harming humans and the environment, and at a price which is cost-effective to the farmer. Only one out of every approximately 20,000 compounds screened shows promise of being commercially viable. It can cost the research company $50 million or more to bring a new product to the market, with absolutely no assurance of market success. The research companies in 1985 alone spent over $500 million on research into safer and more effective products.

It is important to point out what non-research companies get by copying a research company's product. They get not only the registration, but the label as well. Some, but not all, of the costs incurred by the research company in obtaining a registration are covered by data compensation. However, very few, if any, costs of developing the label are covered. What is in a label? Years of performance and safety testing that provide up-to-date information on how to use a product efficiently and safely. For example, how many hours before a rain can a product be applied and still perform? What sort of application equipment works best? What other products are compatible with your product when mixed together? What is the effect of application in high humidity? What effect do different soil pH's have on application? How long after a field is sprayed should a worker wait before entering the field? This is all critical product performance data developed by the research company. It is available to the non-research company at absolutely no cost.

There are other significant costs incurred by the research company but not covered by data compensation. Research companies invest millions of dollars in American universities, testing and resolving scientific issues related to pest management. The results of this investment are available to non-research companies, at no cost to them.

Research companies spent hundreds of thousands of dollars in 1985 and 1986 on state certification programs. These programs were designed to certify farmers for pesticide application. Non-research companies benefited from these programs without paying a dime in support.

Research companies employ thousands of technical support staff, including toxicologists, physicians, industrial hygienists, ecologists, biologists, etc. These individuals provide analytical standards to state and federal regulatory agencies, they establish and operate telephone "hot lines" to respond to emergencies, they have teams to respond to accidental spills, and they provide technical support for ground water monitoring. They also provide customer service to the farmer or dealer, and often--to maintain product integrity--they will respond to problems created by a non-research company's product. All of these services benefit the non-research companies and cost them nothing.

In addition, non-research companies enter--at no cost--a fully developed market. These companies exploit the millions of dollars that research-based companies have spent to educate agricultural users about a product and persuade the users to buy it.

There are also substantial international trade implications of data compensation. Large, off-shore, non-research producers are already playing a significant role in supplying foreign-made active ingredients to the United States. These companies would love to see data compensation modified. It would provide them with cheap, quick and easy access to the American markets. Some examples may be helpful:

- Recently an American research company began an arbitration with what appeared to be an American non-research company. After the proceedings had progressed a while, a large European firm suddenly appeared. It turned out that the European firm had contracted with the non-research company to provide product, and that the American non-research company was doing nothing more than acting as the marketing agent for the European company. When this fact became known, the European company settled the arbitration at a fair value to all parties involved. If data compensation had not existed, the European company would have had easy access to markets normally serviced by American companies.

- Last year, during the beginning debates on FIFRA, an executive of an American research company visited with several of his colleagues from another company in Japan. He was astounded when these Japanese executives knew more about the politics of data compensation than he did; they had a more complete vote count of the Committee than he did; and at various times during the discussion referred to several members of the Committee as "being on our side." Clearly, the Japanese companies saw data compensation as blocking their ability to take American markets from American-based companies.

- Many research companies have data compensation letters in their files from non-research companies which state that they are acting as agents for foreign interests.

The current arbitration system is uniquely suited to look at all the facts in a compensation situation, including whether the real party in interest is a large foreign company looking for an opportunity to enter the American market without having to pay for that opportunity. Elimination of data compensation will drive more production offshore, to the detriment of American production and American jobs.

The non-research companies make several arguments to justify their position. None withstands close scrutiny.

First, they argue that the current arbitration system is unfair. It is difficult for us to see how they can argue that _impartial_ arbitration is unfair. What could be _more_ fair than impartial arbitration? Impartial arbitration favors neither side. The claim that arbitration is unfair attacks the integrity of the arbitrator, since it implies that he cannot render a fair judgment. Do football teams lobby to abolish referees because a call is made against them? If the non-research companies have any validity to their arguments, why are they are so hesitant to make those arguments to an impartial arbitrator?

Second, the non-research companies argue that eliminating data compensation will save farmers money. The figures they cite have little basis in fact. The non-research companies are after eleven products which come off patent between 1987 and 1990. Independent studies have shown that, by 1995, the effect of non-research companies' entry into the market on these eleven products will affect overall prices by no more than 1%. A 1% change hardly seems reason for Congress to cripple research into safe and effective pest control. Moreover, we challenge the assertion that non-research brands save farmers money. A recent study in the _Journal of the_

American Medical Association (reported in the July 1987 edition of "News From the World of Medicine") found that in over two-thirds of the 892,000 drug prescriptions, non-research brands cost more than the research brand. While there may be a temporary price break, what happens when the pest becomes immune to the product? The real cost savings to farmers comes from having more effective technology at their disposal. This technology can come only from research. Pests constantly adapt to older products, and only research can provide the solution. The Southeast Farm Press in a July 1986 article quoted a Georgia farmer as saying, "We have options we never had before, and we can save money because of new chemicals." Non-research companies do not develop the products necessary to lower farmers' costs and to improve safety.

Third, non-research companies argue that pesticides are cheaper abroad than they are in the United States. This is simply not true. They may be able to cite individual cases where it is true, but it is not true across the board. In many cases, a pesticide will sell at a higher price outside the U.S. than within. For example, one product sells for $14.88/kg in the U.S. and for $22/kg in the U.K. and France. Another sells for $4.19/kg in the U.S. and $7.00/kg in Brazil. A third sells for $6.00/kg in both the U.S. and Canada. A wheat herbicide marketed in the U.S. and abroad sells for over 20 percent more in Europe and elsewhere than in the U.S. There are several fungicides which sell for more in Asia than in the U.S. A corn herbicide sells for 50 percent more in Latin America than in the U.S.

There are many reasons a pesticide may be sold at a higher price domestically than abroad, and vice versa. Some products have duties levied on them. For example, the duties on U.S. imports of Parathion were, until recently, 13.8 percent. In other cases, currency fluctuations may cause differentials. Many products which several years ago sold for a premium abroad when the dollar was at record high levels have now gone down in price. In some countries, domestic manufacturers have dramatically lower labor, health and safety costs, and are therefore able to sell for a lower price than an American exporter. In conclusion, there is no basis in fact to contend that data compensation causes products sold abroad to cost less than they do at home, or for that matter that data compensation causes prices to be lower in the U.S. than overseas.

Finally, non-research companies argue that they are asking for the same thing as in the pharmaceutical industry. There are two good reasons to reject this argument.

First, there are vastly different regulatory and marketing situations for pharmaceuticals and pesticides. The products are reviewed by different agencies and have different regulatory burdens. The marketing opportunities for pharmaceutiticals are much larger than for pesticides, enabling research companies in that industry to recoup investment easier and faster. Finally, the market for pharmaceuticals is not driven as much by market forces. A decision on a prescription is made not by the consumer--the patient--but rather by the physician. (How many times have we complained about the price we had to pay for a prescription drug? Nevertheless we paid the price because the doctor ordered it.) The market for a pesticide is dictated by economic forces. The consumer of a pesticide, the farmer, unlike the consumer of a pharmaceutical, is not ordered to do anything, and he makes decisions based on cost-effectiveness and bottom line benefit to him, not on a prescription. Again, this helps the research company in the pharmaceutical industry recoup investment easier and faster.

Second, what's good for the goose, the pharmaceutical industry, may not be good for the gander, the pesticide industry. The pharmaceutical industry is 15 times the size of the pesticide industry and, yet, the cost of developing new pesticide products is the same or greater than that of drugs. In no other industry than drugs is one company required to give its proprietary test data to another without payment. An automobile company is not required to give proprietary test data to another company. Nor is a computer company, or a vacuum cleaner company, or a light bulb company, or any other company, forced to give its proprietary data to another company without payment. Why should Congress force a research-based pesticide company to give its proprietary test data, which cost it tens of millions of dollars to develop, to another company free of charge?

The question in S.1516 and proposed alternatives is simply one of supporting research or of not supporting research. An abundant food supply is the beneficiary of a research-based industry. Research dollars are used to develop newer and safer products. They are used for investigations into biotechnology, with promises of naturally occurring pesticides and pest resistant crop strains. Non-research companies, and their foreign colleagues, do not participate in this research.

Who really has the long term interests of agriculture in mind? The companies which annually devote hundreds of millions of dollars to discovering safer and more effective techniques for growing food? Or companies which do not devote such resources? Preserving incentives for research, as S.1516 clearly does, will serve the long term interests of American agriculture.

PATENT TERM RESTORATION

Another important business issue in S.1516 is patent term restoration (PTR). As with data compensation, PTR was substantially compromised in the 99th Congress. Despite serious misgivings, we continue to support the compromise contained in S.1516, and regret that some of the non-research companies no longer support what they agreed to last year.

The key compromise agreed to by the research and non-research industries in the 99th Congress and incorporated in S.1516 would allow non-research companies to begin testing of a patented product before the patent expires. This was a very difficult compromise for the research companies to accept, since it overturns the 200-year old patent law that any use of a patented product (except for purely intellectual purposes) is an infringement of the patent. Nevertheless, in the spirit of compromise and in the interest of moving a FIFRA bill, we finally acquiesced. Thus, if the non-research company decides not to go through data compensation, or if it goes through an arbitration but walks away from the judgment, it has the option of beginning the necessary tests before the patent expires. This will enable that company to enter the market much sooner than does current law. We fail to see why they cannot agree to what they already agreed to, and we urge the Committee to reject their demands for more.

The non-research companies are also arguing that they will "give" PTR in return for data compensation. What they fail to add, though, is that they are comparing apples and oranges. Another PTR compromise reached with the non-research companies is a provision limiting the application of S.1516 to future products only, i.e., products not yet on the market. Contrast this with the non-research proposal on data compensation, which would apply to all products, future and present. For example, there is a corn herbicide whose patent expires in 1988. It does not enjoy a full 17-year effective patent life, as do most other inventions. But under the provisions of S.1516, the product is not eligible for patent restoration. Nevertheless, the non-research proposal on data compensation would eliminate data compensation for that herbicide, despite its never having had a full 17-year effective patent life.

We strongly support the business provisions of S.1516 and urge the Committee to reject any weakening amendments.

INDEMNIFICATION

Mr. Chairman, we understand that S.1516 proposes to modify the FIFRA section on indemnification by eliminating the presently certain payments to innocent owners of pesticides who suffer losses when EPA suspends and cancels a product. Instead, your bill would require a specific line item appropriation of funds in advance before EPA could make indemnification. This uncertain legislative process and the prospect that indemnification would not be made to innocent owners of pesticides will harm agriculture.

To understand why indemnification is important to agriculture, one must understand what indemnification is intended to do and why it is a reasonable government response to potentially catastrophic losses that threaten the nation's ability to produce food and fibre.

Under the authority of FIFRA, whenever EPA determines that use of a pesticide poses an "imminent hazard," the agency may suspend the registration of a product under section 6 of the Act. You may note in this regard a defect of statutory drafting that has concerned our industry since its enactment in 1972. The law does not adequately define what constitutes an "imminent hazard" and, with this defect, grants EPA expansive powers to immediately and without hearing terminate the sale and use of pesticides if such a condition exists.

Perhaps to mitigate this deficiency and the legal problems it raises and, certainly, to address the unique circumstances of agriculture, on which I will comment in a moment, section 15 of FIFRA requires EPA to indemnify the owner of pesticides for certain losses resulting from the suspension followed by the cancellation of a product. Indemnification is required unless the owner had knowledge that the pesticide did not meet registration requirements and continued to produce the compound without giving such information to the agency. This statutory right extends to all "owners" of pesticides, including manufacturers, formulators, distributors, retailers, farmers, ranchers, and other consumers of pesticides.

One notes three important points with respect to section 15. It only applies to persons who are equitably entitled to such payment and the payment covers only the cost of the pesticide in the hands of the owner. The indemnity provision is not intended to be a windfall to those who produce or sell a product that they know to be dangerous or to compensate owners of pesticides for the many other losses which may be occasioned by the suspension and cancellation of a product. Finally, EPA can--and has--removed pesticides from the market under current law without having the product qualify for indemnification. Indemnification occurs only when there is an "imminent hazard."

Let me turn now to the reasons why indemnification is entirely appropriate and necessary to the public interest. In enacting FIFRA, Congress recognized that there would be inevitable instances where, despite extensive health and environmental tests, careful review and oversight by federal and state agencies, and even long and uneventful use by the public, a product must be suspended and cancelled. This drastic action is not one that anyone can anticipate or desire. Suspensions are triggered by an EPA finding of "imminent hazard," a rare, unexpected, and severe condition. Emergency suspensions are a summary proceeding, may be initiated without any users' or producers' input, and may be effective immediately.

This drastic, but necessary remedy in the face of an emergency must be seen also in the context of agriculture. Our business is seasonal. We must manufacture, store, and distribute an entire year's inventory of most products, to be ready for planting and at other times in the year when farmers and ranchers need pesticides. Our customers cannot wait more than a few days for product delivery.

Usually 1-to-1½ times total annual sales of a product is in distribution, inventory and production for this limited time. That means that for many widely-used products the loss to owners in the value of the product alone could easily exceed $100 million. This figure does not count lost agricultural production, closed manufacturing plants, lost jobs, and unrecovered testing expenses. Even with indemnification, pesticide producers, distributors, farmers and ranchers already absorb these other losses either directly or through increased product prices.

What are the consequences of this situation in view of indemnification? Simple. Each producer of agricultural pesticides and everyone in the chain of distribution, including farmers, stands to lose his investment in inventory and perhaps the business itself if a pesticide is suspended. The loss can be catastrophic.

The seasonal business of agriculture, requiring manufacture and storage of large pesticide inventories, increases the risk of loss beyond the means of most companies and individuals if a major product is suspended and cancelled. Survivors certainly will try to pass the loss along to customers in the price of other products. This sharing of losses with others in the economy will only exist where there are other products and users that can bear the load. Agricultural users of pesticides, however, may not be able to pass the higher costs on to their customers.

I am sure that you, Mr. Chairman, are well aware of the economic hardships of those in agriculture and the difficulty of recovering costs even in good times. Congress recognized this economic limitation in agriculture and importance of vital U.S. food production in enacting the indemnity provision. If it is eliminated or substantially revised, the result will be one more factor leading to more farm and ranch failures and fewer pesticide producers who are able to withstand these large and unexpected financial shocks.

While staggering potential losses are a persuasive reason for Congress to provide indemnification, there is more. All pesticides must be approved by EPA before they are sold. EPA designates what tests on a product are necessary and reviews the test results and other information before the product is registered. The registration of a pesticide is the official determination by this government that the proposed use of the product will not cause unreasonable adverse effects on health or the environment. At registration, both the registrant and EPA have done everything that Congress has required and that is reasonably possible to ensure the product is safe. Thereafter, EPA may suspend and cancel the product because of a change in administration policy, political pressure, new information, or reassessed existing information. Government data requirements, registration, and continuing oversight make EPA a partner with registrants and pesticide users in the resulting losses, if, through no fault of anyone, a product must be suspended and cancelled. Recognizing that indemnification covers only part of the total losses from product suspension, indemnification by the government is small insurance indeed.

We have heard the assertion, as you have, that the federal government should bear no financial responsibility for suspending and cancelling pesticides. The assertion is said to be buttressed by a budget crisis at EPA that suggests that the agency's indemnification responsibilities under FIFRA will bankrupt the pesticide program. Setting aside whether EPA's cost estimate for indemnification is correct, which we have no reason now to challenge, a quick reading of FIFRA section 15 reveals that the crisis is largely manufactured by OMB and EPA. Section 15 does not require indemnity payments from the agency's budget. That obligation is a requirement imposed on EPA by OMB. While indemnification is an obligation of the administrator, it seems to us that the law is silent on what funds are to be used. If there is confusion on this score, perhaps some Congressional guidance on what funds may be used may be in order. The alleged EPA budget "crisis" should not obscure the good and substantial reasons to preserve indemnification under FIFRA.

FOREIGN TRADE IN PESTICIDES

I would like to turn now briefly to a proposal by some environmental interest groups to bar U.S. exports of cancelled, suspended, severely restricted, and unregistered pesticides. Our industry fully supports and actively encourages establishment of effective pesticide registration and enforcement systems in all nations where agrichemicals are used. We are continuing to expand this effort. The major problem with exported agrichemicals, however, especially in developing countries, is misuse. This problem cannot be corrected or controlled by the changes that some environmental lobbyists propose. The reason is simply that the need for agricultural pesticides--those registered and unregistered in the United States--will be met by foreign manufacturers if exports are prohibited here. Barring U.S. exports of unregistered, restricted, and cancelled pesticides will not solve the problem. It will only take responsible U.S. companies out of the limited foreign markets where we are now--where U.S.

companies can provide the kinds of products and training to avoid misuse. Barring exports will only reduce employment available to U.S. workers and remove products from countries that have a considered and legitimate need for the products.

REREGISTRATION FEES

Mr. Chairman, I would like now to turn briefly to the question of increased reregistration fees. S.1516 proposes to permit EPA to assess fees on registrants to cover all or a substantial part of the cost of the federal pesticide reregistration program. You may recall that last year that we agreed to contribute up to $150,000 per active ingredient. The upper limit on this amount has been increased over 5-fold to $750,000. While we support federal budget reduction efforts, we believe that shifting the cost of this element of the federal pesticide program to the pesticide registrants and users to this extent is inappropriate.

There are two important reasons for this conclusion.

First, reregistration fees reflected in the current House bill and in the bills considered by both the House and Senate last year were the result of difficult negotiations and compromise. It was recognized then, as it should be now, that large reregistration fees would cause those in agriculture forced to pay those fees to lose interest in supporting FIFRA amendments. The compromise that was reached last year was an honest effort to help the federal government through a process that would face unacceptable delays without some financial contribution from the private sector. It was expected that the EPA would maintain financial support for registration at current levels and seek expanded support from Congress for the additional effort contemplated in the FIFRA amendments. It appears now that the compromise is being exploited in a grab for more money.

The second and related reason is that the increased fees may provoke certain opposition that has been muted up to now. Many in our industry and others in agriculture have grave reservations about EPA programs and Congressional initiatives employing a "user fee" to raise revenue for government services. While payment of modest fees by those who derive a special benefit from certain government facilities may be appropriate, assessments to fund programs that benefit the general public are not. Last year, when reregistration fees were not a significant financial burden and were viewed as a welcome concession in the interest of compromise, our industry and agriculture agreed, albeit reluctantly to set aside these objections. Now, when it is clear that some wish to saddle us and our customers with EPA's entire reregistration program and, perhaps, the whole federal pesticide program itself, we literally cannot afford the luxury not to object.

CITIZEN SUITS

In closing, Mr. Chairman, I would like to touch briefly upon the issue of "citizen suits" or "private right of action." While currently not in S.1516, some environmental special interest groups have urged that Congress adopt a new federal cause of action for violations of FIFRA, notwithstanding adequate common law and other statutory remedies defining and protecting the rights of the public in instances of pesticide misuse. Apart from the request of these special interests, there has been no convincing argument showing that the provision for citizen suits would materially improve the enforcement of FIFRA or have any other beneficial effect. In fact, the amendment has the potential of adversely affecting government enforcement.

If a citizen suits provision were to be made law, certainly more pesticide users, dealers, and registrants will be sued, but that would not mean that they have violated FIFRA or that FIFRA will be enforced better. In fact, uncoordinated private litigation may interfere with government enforcement priorities, set adverse legal precedents, and make additional demands on court and government resources.

There is no compelling evidence that citizens suits under other statutes have improved enforcement. There is considerable evidence that such suits have been very profitable for environmental attorneys. One environmental attorney was quoted by the Wall Street Journal as bragging, "It's like shooting fish in a barrel, and we've shot lots of fish." Another lawyer said, "These are no-risk lawsuits. It's like going to the bank." Literally millions of dollars have gone to special environmental causes because of these so-called "citizen" suits. Many are settled for their nuisance value.

In 1972, when FIFRA was initially enacted, Congress considered and rejected a citizen suit provision. It believed that FIFRA enforcement should be the responsibility of state and federal governments. Unlike environmental laws, FIFRA regulates millions of people: homeowners, farmers, hospitals, dealers, applicators, and manufacturers. The Senate Agriculture Committee expressed concern that such an amendment would "encourage suits by professional litigants" and "the filing of baseless claims and harassing suits."

If a citizen suit provision were enacted, the increased potential liability exposure to pesticide users, applicators and others, would be tremendous, not to mention the cost of defending against frivolous lawsuits. Presumably, a person alleged to have suffered injury or damage from a pesticide would not have to prove negligence or tortious conduct. Instead, he merely would have to demonstrate that the farmer or other pesticide user in some manner violated the broad (and vague) "use" provision or other requirements of FIFRA.

An imaginative litigant could devise many types of suits under citizen suits authority. For example, FIFRA makes it unlawful to use a pesticide that is "misbranded." An environmental interest group which opposes use of a widely-used herbicide, for example, could allege that the product is "misbranded" under FIFRA because it does not perform its intended function without causing "unreasonable adverse effects." If a court agrees, it could enjoin users from ever using the product. The environmentalists could even try to collect damages for past "misuse" of the herbicide.

Our industry supports the right of injured parties to be able to seek judicial redress against those who may have caused their injury. Suits under the common law for injuries and damages, some meritorious and some frivolous, are nothing new. In virtually all states, moreover, use of a pesticide in violation of government laws and regulations is negligence per se or, at least, strong evidence of negligence. Where an individual is entitled to equitable relief, virtually every state allows its citizens to obtain injunctions against such unlawful or negligent actions. There is no reason to amend FIFRA to permit special interests to frustrate and confuse EPA's and states' enforcement efforts.

CONCLUSION

Again, Mr. Chairman, I wish to thank you and members of this Committee for the opportunity to speak on S.1516 and other important related issues.

Senator HARKIN. Mr. Hagaman, please proceed.

STATEMENT OF JOHN L. HAGAMAN, PRESIDENT, GLOBAL AGRICULTURAL PRODUCTS, THE DOW CHEMICAL CO.

Mr. HAGAMAN. Thank you, Mr. Chairman. As Dr. Early stated, I plan to address two issues in the time remaining: data compensation and patent term restoration, or PTR.

The research industry supports the provisions in S. 1516 on both data compensation and PTR. These provisions are the result of difficult compromises achieved by the Committees on Agriculture and Judiciary in the 99th Congress. Despite some serious misgivings, we continue to support those compromises and we thank you, Mr. Chairman, and Senator Lugar, for your continued support of the provisions. We regret that some of the nonresearch industry cannot agree again to what they agreed to last year.

There are two significant compromises in S. 1516. The first would make the impartial arbitrator's decision nonbinding on nonresearch companies. That is, a nonresearch company would have the option of walking away from any judgment it did not like. I point out that the judgment would still be binding on the research company. The second key compromise in S. 1516 would allow nonresearch companies to begin the necessary tests on a patented product before the patent expires. Although this overturns 200 years of patent law, we finally accepted it in the 99th Congress as a necessary compromise.

Thus, S. 1516 contains two significant advantages for the nonresearch industry—nonbinding arbitration and the ability to start testing before patent expiration. We fail to see how they can reasonably reject this compromise.

The question on the business issues is simply whether or not to support research. An abundant food supply is the real beneficiary of a healthy research-based industry. Only research can provide the newer, safer, and more effective products that are necessary to lower farmers' costs and keep American agriculture competitive.

We urge the committee to support the data compensation and PTR compromises in S. 1516. Thank you.

Senator HARKIN. Mr. Hagaman, thank you very much. Now, Dr. Stickle with the Chemical Producers and Distributors Association.

STATEMENT OF WARREN E. STICKLE, EXECUTIVE DIRECTOR, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION, ACCOMPANIED BY ROBERT D. SHOCKEY, CHAIRMAN OF THE BOARD, DREXEL CHEMICAL COMPOUNDS, MEMPHIS, TN, AND PRESIDENT, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

Dr. STICKLE. Mr. Chairman, my name is Warren Stickle, and I am executive director of the Chemical Producers and Distributors Association [CPDA]. We thank you for the opportunity to discuss our position on FIFRA and the need for generic pesticide registration.

The Chemical Producers and Distributors Association is a voluntary nonprofit membership association consisting of about 50 companies engaged in the manufacture, formulation, distribution, and sale of products used on food, feed, and fiber crops and for lawn and garden care. We are engaged in the formulation, manufacture, and distribution of some $2 billion worth of agricultural pesticides.

Today, I am accompanied by Mr. Robert D. Shockey, chairman of the board of Drexel Chemical Compounds. Mr. Shockey would like to add a few comments with regard to some of our concerns on FIFRA, and I would like to come back at the very end and take a few moments to summarize.

Senator HARKIN. Thank you.

Mr. SHOCKEY. Thank you, Mr. Chairman. We at CPDA strongly support S. 746, the Pesticide Price Competition Act, and we commend Senator Nancy Kassebaum for introducing this legislation and for her fine remarks this morning.

S. 746 would establish an abbreviated generic pesticide registration system, stimulate competition in the pesticide industry, and lower the price of pesticides for farmers, ranchers, users, and consumers. Over the next 5 to 6 years, 22 products will come off patent, representing about 45 percent of the agricultural pesticides used in the United States. If generic products could enter the marketplace, we could save farmers from $400 to $500 million per year for at least the next 5 years on agricultural pesticides alone. Consumers could save additional millions on nonagricultural products.

If we can reduce the price of pesticides by 10 to 20 percent we save farmers substantial sums. For those crops like peanuts, cotton, rice, sugar cane and tobacco, we might be able to save farmers from $5 to $25 per acre on pesticide costs. For large acreage crops like corn and soybeans, we might be able to save $3.50 per acre cost. Generic products or nonproprietary pesticides cost about 50 percent less than patented products. We need to do more to encourage the entrance of generic products into the market so that farmers and ranchers can get lower priced pesticides.

In 1984, the drug industry adopted patent term extension, generic registration, and rolled back the *Bolar/Roche* decision, resulting in increased products, a 14 percent rise in research and development and lower prices for consumers. We believe that drugs and pesticides should be treated on a similar basis.

CPDA'S COMMENTS ON S. 1516

We would like to offer some comments on three concerns: reregistration fees, patent term restoration and the *Bolar/Roche* decision.

REREGISTRATION FEES

We at CPDA are strongly opposed to the registration fee proposal contained in S. 1516. Such a fee proposal would increase by five times the fees contained in H.R. 2463, introduced this year.

S. 1516 does not grant any waivers, exemptions, or adjustments to the reregistration fee schedule for minor use products or for small businesses.

SMALL BUSINESS CONSIDERATIONS

Small businesses are particularly concerned that the adoption of a reregistration fee for pesticides will discourage innovation, will limit the number of products available to distributors and will reduce the number of registrations that a pesticide producer could afford to carry in his product line.

PATENT TERM RESTORATION

Despite our serious reservations about patent term extension, we would support such a proposal if it were included in a compromise package containing generic registration and a complete rollback of *Bolar/Roche* decision. S. 1516 is one-sided in that it benefits large basic manufacturers without offering lower prices to farmers, ranchers, and consumers or making entry for generic products.

ROLLBACK ON THE BOLAR/ROCHE DECISION

If a product is to receive patent extension, as suggested by S. 1516, there should be a full repeal of the *Bolar/Roche* decision. S. 1516 contains only a limited 2-year repeal. Such a limited repeal provides little relief to generic manufacturers, especially if the testing and EPA review take 5 to 7 years leaving us with a 3- to 5-year deficiency.

Those 3- to 5-year de facto patent extensions prohibits market entry, denies small business access to the marketplace, and deprives farmers and consumers of lower priced pesticides.

Additional comments which CPDA would like to offer: first we face a difficult problem in obtaining "me-too" registrations or simple amendments to existing registrations.

Many of these applications or amendments sit in the Registration Division of EPA in excess of a year or more. In many cases, the processing of these items could take only an hour or certainly less than a day. The present backlog is clearly the worst in a decade and threatens to get worse unless Congress takes decisive action.

We believe that EPA needs to redirect its priorities to timely process "me-too" applications and amendments to existing registrations within specifically definable timetables, and should assign some of its registration personnel to the administration of the whole registration process.

Second, we strongly favor H.R. 2869, the Pesticide Data Coordination and Synchronization Act of 1987. This legislation will reduce the cost of pesticides, eliminate duplicative and unnecessary testing, expedite the closing of data gaps, and make sure that pesticides for farmers, ranchers, and consumers, especially minor use products, will be available wherever needed.

Third, we strongly oppose S. 1524, a bill that would allow local political jurisdictions to reduce the sale of the pesticide.

Senator **Harkin**. Thank you, Mr. Shockey.

[The prepared statement of the Chemical Producers and Distributors Association follows:]

STATEMENT OF THE CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION BEFORE THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY, U.S. SENATE, JULY 30, 1987

Mr. Chairman, my name is Warren E. Stickle. I am Executive Director of the Chemical Producers and Distributors Association. We thank you for this opportunity to discuss our position on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the need for generic pesticide registration. We commend this committee for its continued interest in FIFRA amendments.

The Chemical Producers and Distributors Association (CPDA) is a voluntary non-profit membership association consisting of about fifty companies engaged in the manufacture, formulation, distribution and sale of products used on food, feed and fiber crops and for lawn and garden care. We are primarily composed of small- to medium-sized businesses engaged in the formulation, manufacture and distribution of some $2 billion worth of agricultural pesticides.

A majority of our members rely upon the production of "generic" pesticides, those products on which the patent has expired. Our membership provides a much needed service to the agricultural community in formulating and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

Today, I am accompanied by Mr. Robert D. Shockey, Chairman of the Board of Drexel Chemical Compounds, Memphis, Tennessee, and President of the Chemical Producers and Distributors Association.

PART I: THE NEED FOR GENERIC PESTICIDE REGISTRATION

The Pesticide Price Competition Act:

Mr. Chairman, we at CPDA strongly support S. 746, the Pesticide Price Competition Act, a bill introduced by Senators Nancy Kassebaum (R-Kan.) and Al Gore (D-Tenn.) and cosponsored by Senators Sasser and Dole. We applaud them for their leadership on pesticide issues facing this Congress, especially the need to lower pesticide prices for farmers, ranchers, users and consumers, while increasing competition within the pesticide industry, especially for small businesses. An identical bill, H.R. 2569, has been introduced on the House side by Congressman Charles Hatcher (D-Ga.) and 19 cosponsors.

S. 746 would establish an abbreviated generic pesticide registration system, stimulate competition in the pesticide industry and lower the price of pesticides for farmers, ranchers, users and consumers.

The purpose of this legislation is to lower the farmer's cost of production by reducing the costs of pesticides that farmers buy each year and reduce the cost of non-agricultural products that consumers buy in their grocery and hardware stores. This measure could save farmers from $400 million to $500 million per year for at least the next five years on agricultural pesticides alone. Consumers could save additional millions on non-agricultural products.

It appears the Administration also generally approves this approach. In a letter dated March 10, 1986, Health and Human Services Secretary Otis Bown wrote to Senator Strom Thurmond (R-S.C.) about restoring patent time lost due to federal premarket requirements for veterinary drugs, pesticides and agricultural chemicals. "In summary," wrote Secretary Bowen, "we support patent restoration for veterinary drugs, but urge the Congress to add an additional provision that would enable manufacturers to obtain federal premarket approval to market generic versions of these drugs without having to duplicate the potentially costly and time-consuming safety and effectiveness studies that are required of manufacturers...without such a provision, there would appear to be no need for patent restoration since the current federal requirement for duplicative testing would continue to serve as an effective economic barrier to competition even after the expiration of patents that would be restored by this legislation," concluded Secretary Bowen.

"Patent restoration would have little meaning, however, if federal regulatory barriers had the effect of preventing the marketing of virtually identical generic products after patents expire," Bowen observed. "We have concluded," Bowen pointed out, "therefore, that both patent restoration and an abbreviated approval procedure ought to be included in the same legislation so that they may be considered and, hopefully, enacted together."

Secretary Bowen noted: "We continue to believe that it is good public policy to link the two concepts in order to foster research for new products and, at the same time, encourage competition and lower prices. In our view, it would be unfair to consumers as well as to the industry as a whole if one were enacted but not the other, or if a substantial time lag occurred between the enactment of both." Mr. Chairman, I request that the full text of Secretary Bowen's letter appear in the hearing Record following my remarks. (See Appendix I).

As we look across our land, we discover an agricultural and rural economy suffering from problems--increasing costs of production, growing debts, more problems obtaining adequate credit, declining prices for crops--and we need to move forward to address these concerns. One way to help the farmer address the increasing costs of production is to face the problems head-on. By amending the pesticide legislation, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), it is clearly possible--even desirable--to increase competition in the pesticide industry, resulting in reduced pesticide prices and lowering the farmer's cost of production, without costing the government a penny!

Should we give farmers a break? Should we join together to reduce the cost of pesticides for our farm community? Should we seek to lower the farmer's cost of production? Is it time that the Congress act to alleviate some of the economic distress facing rural America?

Increased Competition Will Reduce Pesticide Prices:

Farmers across this country apply agricultural pesticides to their crops and these costs are a significant percentage of the cash variable expenses (seed, fertilizer, chemicals, hired labor, etc.) that farmers pay each year. According to the recent figures gathered by the Economic Indicators of the Farm Sector, Cost of Production, 1985, prepared by the United States Department of Agriculture, pesticides average between 10 and 35 percent of the cash variable expense. For soybeans, farmers spend $17.47 per acre for chemicals, equalling 32.3 percent of the cost of production. For peanuts, farmers nationwide spend about $80 per acre for agricultural chemicals or about 30 percent of their cost of production. For cotton, farmers spend $45 per acre or 21 percent of their cost of production for pesticides. For sugar cane, it is $56, and for rice it is about $27 per acre. For corn, it is about $18 per acre, or almost 9 percent of their cost of production. Farmers also apply significant amounts of pesticides for tobacco (burley - $70 and flue-cured - $94). For wheat, it is almost $3 per acre for agricultural chemicals. In essence, farmers spend a considerable amount of their cash reserves on pesticides.

In the southeastern section of the country, farmers face an even greater challenge. While cotton farmers across the nation average $45 per acre for chemicals, farmers in the southeast apply $96 of pesticides per acre. Peanut farmers average about $80 per acre for chemicals, but southeastern peanut farmers average almost $95 per acre. Virginia and North Carolina farmers average almost $89 per acre. Southeastern farmers, like the Hawaiian sugar cane growers and Texas sugar beet producers, pay a disproportionate share of their cost of production for agricultural chemicals.

If we can encourage the development of generic pesticides, we can lower the prices of pesticides that farmers buy and reduce the farmer's cost of production. It may be possible to reduce the price of pesticides by 10 to 20 percent or more. For those crops like peanuts, cotton, rice, sugar cane and tobacco, we might be able to save farmers from $5 to $25 per acre in pesticide costs. For large acreage crops, like corn, soybeans and wheat, we might be able to save farmers almost $3.50, $3.50 and $.60 per acre respectively. Without doubt, however, we can help the farmer reduce the cost of production at a time when the cost of most items purchased by the farmer have been rising higher and higher. Please see Appendix II.

One way to reduce these costs is to amend the data compensation section of FIFRA. When generic pesticide producers enter the market following the expiration of a patent, they generally capture only 10 to 20 percent of the existing market. (Ciba-Geigy sells more atrazine products in pounds now than when the patent expired eleven years ago.) With the fear of losing more of a market share, the overall impact on reduction in prices can be significant.

Generic Pesticides' Impact on Corn Crop:

Mr. Chairman, rather than discussing each farm commodity, we would like to briefly discuss the impact that generic pesticide registration would have on the corn crop as a case study.

American corn growers, on average, applied about $17.58 of agricultural chemicals per acre of corn (1985 figures). It represented about 8.6 percent of a corn grower's cash variable expenses.

We believe that increased competition and generic pesticides could result in significant savings for corn growers. If we could reduce the cost of pesticides by 20 percent, corn growers could save about $269.9 million per year, or about $3.50 per acre. Appendix III, based on 1986 corn acreage, gives a state by state breakdown of these savings. The largest saving would be in Iowa, Illinois, Nebraska, Minnesota, Indiana, Ohio, Wisconsin and South Dakota.

Pesticide price reduction will reduce the corn grower's cost of production and increase his net receipts. Based on a national average, corn growers would be able to increase their net receipts by about 6 percent per acre.

As can be seen in Table I, corn growers in Minnesota would experience an increase in net receipts of 7 percent per acre, with Nebraska at 6 percent, Iowa and Indiana at 5 percent and Illinois at 4 percent.

TABLE I

PRODUCTION COSTS AND NET RECEIPTS PER PLANTED ACRE IN 1985

(NOTE: All figures in dollars)

	Cash Receipts	Cash Expenses Total	Cash Expenses Chemicals	Receipts Less Expenses
Corn				
Illinois	310	224	18	85
Indiana	276	203	18	72
Iowa	270	200	20	70
Minnesota	241	189	19	53
Nebraska (dry land)	159	95	13	64
U.S. average	260	205	18	55

20 percent Pesticide Cost Reduction

	Estimated Savings	Percent Increase in Net Receipts
Corn		
Illinois	3.52	+4
Indiana	3.52	+5
Iowa	3.52	+5
Minnesota	3.52	+7
Nebraska (dry land)	3.52	+6
U.S. average	3.52	+6

These pesticide cost reductions will not come at the same time since they are dependent on pesticides coming off patent and generic pesticides entering the marketplace. Over the next five to six years, 22 products will come off patent, representing about 45 percent of the agricultural pesticides used in the United States. Many of these pesticide products are used on corn.

In 1986, Furadan came off patent and, in December, 1987, Lasso will come off patent. In 1988, Bladex and Bolstar will come off patent. In 1991, Roundup's patent expires. In 1992, Prowl's patent expires and, one year later, Dual's patent runs out. These seven pesticide products are widely used on corn, as well as other crops. See Table II.

TABLE II

PRODUCTS TO COME OFF PATENT 1986-1993

Trade Name	Common Name	Registrant	Patent Expires	Effective Patent Life
Furadan	Carbofuran	FMC	1986	17
Lasso	Alachlor	Monsanto	1987	17
Bladex	Cyanazine	Shell/DuPont	1988	15
Dual	Metolachlor	Ciba Geigy	1993	17
Prowl	Pendimethalin	Am. Cyanamid	1992	16
Bolstar	Sulprofos	Mobay	1988	8
Roundup	Glyphosate	Monsanto	1991	17

If generic pesticides can enter the marketplace to compete with these seven pesticides, the corn grower will see the greatest benefits since the price reductions for atrazine, with a significant increase in net income.

A quick review of four leading products clearly indicates the savings that corn growers could achieve. If generic products can enter the market and reduce prices by 20 percent, the biggest saving would occur on Lasso and Dual. Together these farm products could save farmers up to $208 million per year.

TABLE III

IMPORTANT PRODUCTS USED ON CORN

	Lasso	Dual	Bladex	Roundup
Amount of lbs. per gallon of active ingredient	4 lbs.	8 lbs.	4 lbs.	4 lbs.
Total lbs. used in U.S. in 1982 according to USDA	85 M	38.1 M	4.9 M	8 M
Retail price per gallon (1987)	$19.70	$49.20	$18.70	$65.90
Savings (total lbs. divided by 4 x retail price x 20%)	$83.7 M	$46.9 M	$4.6 M	$26.4 M

Generic products or non-proprietary pesticides simply cost less. According to the 1986 Industry Profile Survey, produced by the National Agricultural Chemicals Association (NACA), generic products cost less than one-half of proprietary products. In 1985, generics were 52.5 percent less and, in 1986, they were 52.4 percent less.

TABLE IV

GENERICS COST LESS

	1985			1986		
	Prop.	Non-prop.	Total	Prop.	Non-prop.	Total
Sales dollars (millions)	2376.7	1036.6	3413.3	2246	1188.8	3434.8
Pounds a.l. (millions)	364.5	334.8	699.3	324.6	346.6	671.2
# of companies	21	21	26	22	22	26
Average cost per lb.	$6.52	$3.10	$4.88	$6.92	$3.43	$5.12
	52.5 % less			51.4 % less		

Generic Pesticides Lead to Price Declines in the 1970s:

In April 1977, Donald I. Baker, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, wrote to a member of Congress and reviewed the impact that patent expiration had on prices. "Prior to the 1972 amendments," wrote Baker to former Congressman Floyd Fithian (D-Ind.), "when generic producers could economically manufacture technical pesticides upon expiration of the patent, prices typically dropped dramatically upon patent expiration (emphasis added)." Baker further concluded:

> "For example, the price per pound of DDT fell to about 1/4 of the pre-expiration price per pound when competition was introduced, suggesting that monopoly profits were quite significant (and likely adequate to cover registration costs.)" Please see Appendix IV.

During the 1970s, a major pesticide--atrazine, an 80 percent wettable powder (produced by Ciba Geigy)--was used by farmers to control weeds for corn and sorghum. During the early 1970s, the price of atrazine was essentially constant, with minor flucuations. In 1977, the price dropped from $2.50-$2.75 a pound to about $2 per pound, a decrease of at least 20 percent. Other pesticides, according to the General Pesticide Index, were increasing by 8 percent in 1977.

The decline in atrazine prices is attributable to the expiration of the patent in 1976. Robert Lee, Economic Analysis Branch, EPA, concluded:

> "With such a large share of the market in a major crop like corn, entry by additional firms is expected, resulting in a smaller share in the atrazine market for Ciba Geigy and further declines in price."

The national market for atrazine was about 100 million pounds in 1977. A drop in price of 50 cents per pound saved $50 million. For those farmers that used atrazine, there was a saving of $1.25 to $1.50 per acre. A farmer with 500 acres of corn saved $625 on his cost of atrazine. If the patent on atrazine had been extended for five years, farmers would have had to pay an additional $250 million in higher prices. See Appendix V.

In addition, Robert Lee further pointed out that following patent expiration, the price of maleic hydrazide--a growth retardant on tobacco, onions and potatoes--fell dramatically by 118 percent from the last year of patent protection to the first year without protection. He concluded that the decline in price "can be attributed to the expiration of its patent." This was due to both small domestic companies (Drexel, Cumberland, Fairmont) and imports starting a generic market.

During the 1970s, other products coming off patent experienced a decline in prices. Diuron (DuPont) and Simizine (Ciba Geigy) showed significant reductions. Diuron dropped from about $3.25 per pound to about $2.40 per pound, a drop of 85 cents per pound, or 26.2 percent. Simizine declined from $15.00-16.00 per gallon to $9.00-10.00 per gallon, a decline of about $6 per gallon or about 40 percent.

The 1970s provides a clear example when prices dropped after the patent expired, resulting in millions of dollars in savings for farmers, ranchers, users and consumers.

Another pattern also emerged during the 1970s. In 1977 and 1978 the basic manufacturers argued that they needed additional protection and asked Congress to enact a 10-year exclusive use period followed by a five-year period of compensation. In 1978, Congress passed legislation containing these provisions.

"It is curious," remarked Donald Baker of the Department of Justice, "that the asserted need for protection of the test data [1977] became evident only when significant numbers of pesticide patents began to run out. We find the disincentive argument somewhat disingenious."

During the 1970s, two patterns emerged: 1) prices declined after the expiration of the patent, thus benefitting farmers and consumers, and 2) the industry demand for protection occurred when patents were beginning to run out.

And these 1970s patterns have continued into the 1980s as well.

Generic Pesticides Lead to Price Declines in the 1980s:

During the 1980s, some major agricultural products came off patent and generic producers, with great difficulty, entered the marketplace, significantly reducing the price for consumers and farmers. The following chart clearly indicates that these three pesticide products have dropped an average of 18.1 percent.

TABLE V

Product Trade Name and Year Entered the Market

	Phostoxin (1982)	Treflan (1985)	Sutan (1984)
Pregeneric prices	30.20/kg.	28.50/gal.	19.89/gal.
(Prices after generics entered the market, '86)	24.28/kg.	21.43/gal.	17.90/gal.
Percent change in price	-19.6%	-24.8%	-10.0%

Average Price Decrease = 18.1%

When generic products enter the marketplace, pesticide prices decline. Many other agricultural chemicals, presently under patent, are, however, experiencing price increases. The following chart for three pesticides selected at random (and representative of products used in U.S. agriculture) shows that their average price increase was about 9.9 percent between 1983 and 1986.

	Product Trade Name		
Year	Furdan	Lasso	Lorsban
1983	$40.72/gal.	$17.73/gal.	$26.80/gal.
1984	46.69/gal.	18.59/gal.	30.21/gal.
1985	44.82/gal.	18.61/gal.	29.59/gal.
1986	45.77/gal.	18.06/gal.	30.93/gal.
Percent change in price	+12.4%	+1.9%	+15.4%

Average Price Increase + 9.9%

During the 1980s, we have witnessed a continuing pattern of price reductions when pesticide products have come off patent, while other pesticide prices have increased.

It is ironic that, in the period between 1984 and 1987, the basic manufacturers have begun another major effort to protect their monopolistic control of the marketplace by requesting Congress to enact patent term extension, an effort to recover up to five years of time lost in the regulatory process at EPA. It just happens that over the next five years (1987-1991) about 21 pesticides--some of the most widely used and most profitable--used by the American farmers will come off patent. These pesticides constitute about 45 percent of all pesticides used by farmers today.

Hard cost estimates are difficult to come by, but by analyzing past experiences when pesticides have finally been produced by generic manufacturers and also by comparing domestic price levels with the prices that major producers charge for their product overseas, it is clear that a vigorous competition in the pesticide industry would significantly lower the price of generic pesticides to farmers, possibly by as much as $2 billion over the next five years.

Congress has an opportunity to correct this inequity by amending the current law to provide for a reasonable compensation to be paid by generic producers.

American Farmers Face Stiff International Competition:

As competition in any market develops, the price of the product generally declines. Currently, a farmer in Central or South America is paying a lower price for his pesticides than an American farmer. As an example, insecticides being used on cotton are selling for $1.00/lb. overseas and for $1.55/lb. in the U.S. An insecticide for the control of malarial mosquitos sells for $.80 to $.85/lb. overseas and $1.60/lb. in the U.S.

Once product comes off patent, its price can be expected to move closer to the world market price. The following list shows examples for U.S./foreign price differentials which exist now for several products. The U.S. price is expected to move toward the more competitive foreign price.

The following are products and comparison prices:

Product	U.S. Price	Foreign Price
Malathion	$1.55-1.65/lb.	$.82-.95/lb.
Methyl Parathion	$1.55/lb.	$.92-1.05/lb.
Carbaryl	$2.55/lb.	$1.85/lb. (Spain)
Treflan	$26.00/gal.	$16.00/gal.
Paraquat	$32.00-36.00/gal.	$13.00/gal.

There are also products that, while still patented, nonetheless exhibit a large price difference between U.S. and foreign markets since the patent is not enforced outside the U.S.:

Product	U.S. Price	Foreign Price
Roundup	$68.00/gal.	$42.00-44.00/gal.

Anticompetitiveness and Monopolistic Tendencies of the Pesticide Industry:

We are trying to increase competition in the pesticide industry by addressing business issues which have a direct impact upon the ability of our members to conduct business. Without changes in the data compensation area (generic pesticide registration, 3 (c) (1) (D) and 3 (c) (2) (B)), our members will be at a decided economic disadvantage due to these artificial barriers to generic products.

Studies have shown the anti-competitive nature of the pesticide industry (Eichers, 1980). There has been a redistribution of profits in favor of chemical producers and away from formulators and distributors (the percentage of each consumer dollar going to basic chemical producers increased from 45 percent in 1965 to 66 percent in 1976). There also appears to be increasing forward vertical integration in the pesticide industry. About 50 percent of all formulators are now controlled by basic producers through either direct ownership or contractual obligation (Eichers, 1980, p. 13).

Even when patents expire, new entry into the market may be difficult in some cases because generic producers must still register their version of the chemical with EPA. The EPA has attempted to reduce the time lag by using data submitted by the original registrant under 3 (C) (1) (D) of FIFRA. This action in turn has stimulated law suits brought by the original registrants who insist on receiving compensation for the data. Such legal action can insure that generic registrations are delayed in court for a lengthy period, effectively lengthening the life of a patent (Butler letter, March 20, 1986, to Senator Charles Mathias, Jr.).

The pesticide industry is highly concentrated with ten companies controlling 66 percent of the world pesticide market. The U.S. market had been maintained in a fairly competitive mode before 1978 due to the moderate rate of turnover of leading products, allowances for generic registrations under section 3 (C) (1) (D) of FIFRA and patent expiration. However, unreasonable data compensation decisions under section 3 (C) (1) (D) are reducing the number of new entrants into the market on non-patented pesticides. As competition in the market decreases, the incentive to be innovative also decreases, a generally recognized empirical result of most industrial organization studies.

Today, technology and data are protected under Section 10 of the present FIFRA law. The major companies would have you believe that technology is being exported by allowing the use of data for a generic registration when, in fact, technology and data are being imported into the United States.

The top ten agricultural chemical companies in the world are:

Company	Country	U.S. Name
Bayer	German	Mobay
Ciba Geigy	Swiss	Ciba Geigy
Monsanto	U.S.	Monsanto
Shell	U.S.	DuPont
ICI	British	ICI America
Rhone Poulenc	French	Rhone Poulenc
Dow	U.S.	Dow
Hoechst	German	American Hoechst
DuPont	U.S.	DuPont
BASF	German	BASF

The top three companies, Bayer, Ciba Geigy and Monsanto, account for 31 percent of the world pesticide sales. The next seven companies accounted for the next 35 percent of sales worldwide. These ten companies hold a total of 66 percent of the world's pesticide sales, seven of which are not American companies. Technology is actually coming from abroad. These same ten companies are the largest importers of pesticides into the U.S. The NACA Industry Profile Study states that U.S. sales on non-U.S. production have remained about the same: $1,379 million in 1983, $1,366 million in 1984, and $1,318 million in 1985, or about 25 percent of U.S. production.

The Need to Adopt an Equitable Standard for Data Compensation:

FIFRA does allow an alternative to the manufacturers of generic pesticides if they wish to enter the market without replicating the data. In that event, the generic manufacturer must offer to pay compensation to the holder of the data (product is patent free) so that EPA may refer to that data in their files in considering an application for registration by a generic manufacturer. Section 3 of FIFRA, however, set no clear standard for the compensation that must be paid. Using general accounting practices, the data producer can write off the cost of data development in the year the cost is incurred, thus leaving the public financially responsible for the cost of the data. With the general public actually paying the cost of the production of the data, these data should be in the pubic domain, thereby allowing generic registration.

We need an amendment that explicitly and unambiguously confirms the Congressional intention that reasonable compensation for data under section 3 (c) (1) (D) of FIFRA should be fair and equitable.

When a company decides to enter a pesticide market, after the expiration of the patent, it must be able to determine all of its potential costs in order to make a sound business decision. It can define (1) the manufacturing process, (2) raw material costs, (3) cost of plant construction, (4) general overhead, and (5) potential market. While these times are sufficient in most businesses, there is one important element missing for a pesticide product: data compensation for the use of data submitted by another registrant to support the registration of your product.

On its face, FIFRA provides that, if a registrant relies upon data submitted by another registrant, he must offer to pay compensation to the original data submitter. The statute does not provide a definition of "reasonable compensation." If the parties involved cannot reach an agreement, then either one may request that the matter be submitted to binding arbitration before the Federal Mediation and Concilation Board which is to determine "reasonable compensation."

We believe the prior history of FIFRA makes it clear that this compensation is to reflect solely the original data submitter's production cost. The lack of an express standard in the statement, however, has allowed considerable mischief. The only data compensation case which has been specifically decided by binding arbitration, to date, is Stauffer Chemical vs. PPG Industries, Inc. (Stauffer/PPG). The Stauffer/PPG case was heard before a panel of three arbitrators. The final decision against PPG provided for:

- PPG to pay 50 percent of the cost of the data relied upon by the EPA to register their product which had been submitted by Stauffer and was in the Agency's files. The data in question was valued at $2,930,000 and PPG was ordered to pay $1,465,000 to Stauffer within 30 days of the final decision (NOTE: The data which Stauffer had submitted is not sufficient to fully register the product under section 3 of FIFRA and will require PPG to possibly develop or replace several million dollars worth of data when the registration standard is finalized by the EPA).

- The arbitrators ruled that PPG had gained a market advantage by not having to wait the five to seven years necessary to develop the data themselves and obtain EPA

> registration. They also ruled that, since PPG had gained valuable time by relying upon Stauffer's data and having the benefit of their registered labels to copy. To compensate Stauffer for the market advantage PPG gained by relying upon Stauffer's data and labels, the arbitrators awarded them $0.15 per pound of technical produced or purchased by PPG during the ten calendar years from 1983 through 1992. The price per pound is to be adjusted annually based on the change in the Producer Price Index using November 1982 as the base year.

It is important to note that the $0.15 per pound awarded was determined by the arbitrators based upon a net profit by PPG of $0.60 per pound of technical. This is equivalent to 25 percent of PPG's net profits. No allowance was made in the decision for a drop in the net profit to below the projected $0.60 per pound. If PPG's net profit dropped to $0.30 per pound, they would then by paying Stauffer 50 percent of their net profits.

The cost of the actual arbitration process must also be considered. The fees charged by the three arbitrators and the American Arbitration Association (AAA) in the Stauffer/PPG case were $96,000. Stauffer and PPG split this cost with each paying $48,000. It is estimated that the legal fees for PPG in this matter would have been approximately $300,000. The hearings lasted 20-22 days and the case was months in preparation. This estimate of PPG's costs in this matter does not include their in-house administrative costs.

Based upon the above figures and estimates for sales contained in the arbitration decision, PPG's intial costs for data compensation and arbitration were $1,813,000 plus an additional $7,087,500 in royalty payments during the first five years of sales. If PPG's sales remained stable during the ten-year period in which royalty payments are to be made, the total cost to PPG for data compenstion would be approximately $15,988,000 or 5.4 times the cost of the data involved. Is this decision fair and equitable? We think not!

Recently a second case has been submitted to the arbitrators by E.I. du Pont De Nemours & Co., Inc. against Griffin Corporation and Drexel Corporation. In this case, Du Pont is asking:

- $3,000,000 from each of the companies, or 25 percent of its estimated development cost for the data plus;

- a royalty of $1.50 per pound of pesticide sold containing linuron sold by the respondents during the first five years of sales.

As can be seen by the above two cases, it would be very difficult for a small company to decide to enter a market previously held by a major producer. The cost of such an arbitration award under the law would be out of reach of a small businessman. If he were successful in obtaining entry into a market, he could still be faced with future development of several million dollars worth of data when the registration standard for the product was issued, and when he was required to reregister his product.

We believe that a decision such as the Stauffer/PPG decision is totally outside of the intent of Congress when it passed the requirements for reasonable compensation in 1972, or when the statement was amended in 1975 and 1978. We believe the intent of this section was to allow a company which relied upon data submitted to the Agency by another registrant to share in the cost of development of that original data and not to reward the original registrant for being the first to register the pesticide product. We contend that such reward is the purpose of the patent laws and not FIFRA.

Reasonable compensation should be an equitable sharing of the costs of the data. In the opinion of Justice Sandra Day O'Conner written for the Supreme Court, Union Carbide vs. EPA case, Justice O'Conner cited legislative history on this point which we believe is controlling. The Court was not, therefore, called upon to squarely address this issue and did not. The present reauthorization gives the Congress a chance to now expressly clarify the compensation standard to the benefit of all, and we urge that you do so.

The Need to Repeal the Bolar/Roche Decision:

Current patent law allows the recipient of a pesticide patent an exclusive life of 17 years. Basic supplier companies have requested legislative changes to this law by asking that up to five additional years of patent life be added to the pesticide product. The intent of the legislation is to restore lost patent life resulting from the lengthy regulatory review period needed to obtain EPA approval. While a product is being reviewed, it cannot be marketed.

In addition to the anti-competitive nature of the present system of determining data compensation, a recent decision by the United States Court of Appeals has brought into question the practice of developing data necessary to support the registration of an identical pesticide product prior to the expiration of a patent.

On April 23, 1984, the United States Court of Appeals for the Federal Circuit handed down a decision in Roche Products, Inc. Vs. Bolar Pharmaceutical Co., Inc. ruling that the use of a patented product by a second party to develop data for the purpose of obtaining an early market entry following the expiration of a patent was a violation of the "use" provisions of the law. The Court held that, while there was an exemption for the use of a product for scientific purposes, the exemption did not apply when the information gained was for commerical purposes. This decision prohibits the manufacturer of a generic pesticide from developing any data which would be necessary for the registration of one product prior to the expiration of its patent.

This court decision effectively adds a period of up to seven years to the term of a patent, in addition to the proposed five-year extension, totaling a patent life of 29 years if the bill should become law. The following scenario demonstrates a 29-year period of protection:
....Regular patent, 17 years....17 years
....With patent term extension....22 years
....Bolar/Roche cost of time 5-7 years....29 years

In section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984, provisions were included to overrule the Bolar/Roche decision. Essentially those provisions stated that it would not be an act of infringement to make, use or to sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs.

If a product is to receive patent extension, as originally proposed by H.R. 2482 and S. 2792 (99th Congress), or as proposed in H.R. 1345, introduced by Congressmen Frederick Boucher and Michael DeWine, or S. 1516, there should be a full repeal of the Bolar/Roche decision. These legislative vehicles do not, however, contain a full repeal, but only a limited repeal for just two years. Such a limited repeal provides little benefit to generic manufacturers, especially if the testing and EPA review take five to seven years, leaving us with a three to five year deficiency.

In addition, the Bolar/Roche decision also does not allow the generic manufacturer to submit his test results for EPA review prior to the expiration of the patent. Congress wisely created the generic pharmaceutical industry following patent term restoration and we feel that such a move within the pesticide industry would benefit all users.

We at CPDA believe that a generic manufacturer in the pesticide industry should be on an equal footing with drug manufacturers and do the testing and file an application for registration before the expiration of a patent, as long as there is a prohibition against marketing before the patent expires.

These de facto circumstances created by Bolar/Roche clearly prohibit market entry, deny small businesses access to the market place and deprive farmers and consumers of lower priced pesticides.

An important point to remember when thinking about patents is that there can be multiple patents on a compound. A company in the pesticide field will first apply for a composition of matter patent, then a manufacturing patent, a third patent and possibly a fourth on the intermediates used to manufacture the compound. A use patent would be next and then a formulation patent would be requested. With five patents on one compound, separated by a few years, a company would essentially end up with a patent in perpetuity. Does anyone really need patent term restoration?

Importantly, all formulations of a pesticide containing the identical active ingredient should be considered the same pesticide, and no pesticide should be subject to more than one patent extension. In no event shall more than one patent be extended for the same regulatory review period for any product.

We recommend inclusion of an amendment to S. 1516 to redress the deficiencies of the Bolar/Roche decision, as outlined in Appendix VI. If this type of amendment is not included in S. 1516, there is no need for patent term restoration. In effect, the basic manufacturer of the pesticide ALREADY has an extension of the patent by virtue of the period of time required to replicate the test data and obtain an EPA registration prior to bringing the pesticide onto the market. Under the present circumstances, it is nearly impossible for a generic manufacturer to develop his own set of data.

Generic Pesticide Registration will NOT adversely affect Research and Development:

Research intensive chemical companies claim that they need the enactment of patent term restoration so they can increase innovation.

In 1986, the Committee for Research and Development of Agricultural Chemicals, composed of 11 basic manufacturers, warned the Congress:

> "If Congress amends the FIFRA to allow low-cost access to health and safety data for follow-on registrants,...private sector R&D in agrichemicals will decline by $100 million or more each year -- from a base of $553 million in 1985..."
> (See Appendix VII, page 3).

These misleading statements from the agrichemical industry leaders are reminiscent of the statements issued by the drug manufacturers during the congressional debate in 1983-1984 about establishing generic drug registration. What did the Pharmaceutical Manufacturers Association (PMA) state on July 25, 1983? The following statements represent their views on R&D in 1983:

> "Innovation will dry up."
>
> "...it [H.R. 3605] nonetheless strives to reduce economic incentives for important pharmaceutical research still further."
>
> "But whatever short-term savings may be acheived will come at an enormous long-term cost to the public in terms of reduced pharaceutical research, fewer new medicines in the future..."
>
> "H.R. 3605 would substantially reduce the attractiveness of investing in new drug research."[1]

[1] Portion of statement of the Pharmaceutical Manufacturers Association (PMA) before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, on H.R. 3605 on July 25, 1983.

But has R&D in the pharmaceutical industry dried up in the last few years or in the period since the passage of the generic drug bill? What are the facts?

Since 1984, there have been no declines in drug research and development funds, only increases--about 14 percent per year for 1985 and 1986!! In the past two years, an additional $1 billion has been poured into R&D. Research and development has actually doubled since 1981! And has doubled nearly every five years since 1961!!

TABLE VI
R&D IN THE DRUG INDUSTRY

	R&D Human & Veterinary (millions)	Percentage increase	Actual increase
1986	$4,647	13.95%	569,000,000
1985	$4,078	13.94%	499,000,000
1984	$3,579	10.86%	361,000,000
1983	$3,218	18.97%	444,000,000
1982	$2,774	18.00%	433,000,000
1981	$2,340	18.36	363,000,000

(See Appendix VIII).

In 1984, Congress provided the pharmaceutical industry with patent term restoration. This law contains not only the restoration of time lost to regulatory review, but also eliminated the Bolar/Roche decision, and provided accelerated registration which we call "generic registration." The pharmaceutical industry appears to have prospered. Research and development funds have increased year after year. Two hundred fifty-four Abbreviated New Drug Applications (ANDA) appeared at the FDA within the first days after enactment.

In fact, the amount of generic applications rose from 470 in 1984 to 1,069 in 1985, an increase of 127.45 percent. Of these 1,069 applications, 389 were approved. In 1986, there were 1,062 generic applications, but 616 were approved. The effect was delayed because it takes 14 to 17 months to register a generic product. This trend is expected to continue.

The new drug laws allow companies to make generic versions of off patent brand name drugs if they can prove to the FDA that their versions are equivalent to the brand name products. The requirement to repeat the studies to prove the safety and efficacy of established pharmaceutical compounds is no longer required. These new rules have created a new wave of the future for the pharmaceutical industry; Ciba Geigy, Smith Cline, American Cyanimid's Lederle Laboratories, Glaxo and Hoechst have all jumped into the generics marketplace because this is the place for future growth. (Ciba Geigy, American Cyanimid and Hoechst are also pesticide manufacturers and members of NACA). Additionally, several major U.S. drug patent holders have applied for patent term extension. It appears that the law is working as intended by Congress.

Will the major agricultural chemical companies who are producing these new products stop research and development if they do not receive extension of their patients? Will these same companies stop researching and developing new products if generic pesticide registration passes? Will they slash their R&D budgets by $100 million per year over the next several years? We think not!

The existing tax laws provide major incentives for research and development through favorable deductions and tax credits. A large amount of the cost of research and development is the cost of personnel. Salaries, bonuses and the expenses for R&D personnel may be written off under the tax laws in the year in which costs are incurred. Similarly, materials used in R&D may be written off in that year. These write-offs are all R&D costs, not just for costs of commercialized products. The costs of facilities where R&D is performed are capitalized and written off against taxes over several years. In addition to these benefits, investment tax credits are provided under the tax laws for any R&D that exceeds the R&D in a base period.

We agree that the generation of data costs a great deal of money, but who actually pays for the data? Using generally accepted accounting practices, the costs of R&D is usually written off in the year the costs were incurred, up to 50 percent. There is also an R&D tax credit which provides another

25 percent write-off up front. This could mean that 75 percent of the cost of data is paid for by the American taxpayer.

A central argument raised in favor of patent term extension is that innovation is declining under existing law. The amount being spent on research and development is not declining. The U.S. chemical industry (including, but not limited to, pesticides and other farm chemicals) boasted profits of $4.25 billion in 1986, an 8 percent increase over the previous year. Other companies in the Business Week (June 22, 1987, pp. 144-145) survey reported profits as high as 15 percent above 1985 profit levels.

Another gauge of the state of the chemical industry is R&D expenditures for the year. The average annual R&D expenditure was 6 percent higher in 1986 than it was in 1985, with some companies posting R&D expenditures as high as 11 and 14 percent above the previous year, according to Business Week. The chemical industry appears to have no need to worry about a potential increase in R&D following the implementation of generic registration, given these figures.

Also, chemical companies are pouring a considerable percentage of their profits back into R&D. In fact, the industry reported that an average of 48.6 percent of its pretax earnings went directly into its R&D facilities during 1986. That's right, nearly one-half of the nation's chemical industry's profits went directly into research for creating new chemicals, chemicals that will benefit U.S. consumers and U.S. farmers. Some members of the chemical industry reported even higher figures. One company in the Business Week survey reported that 95.9 percent of its pretax earnings were recycled to its R&D facilities. Do these figures reflect an industry where R&D is "drying up?" We think not.

TABLE VII

CHEMICAL INDUSTRY PROFITS AND RESEARCH AND DEVELOPMENT

Company	Profits			R&D	
	1986 (millions of dollars)	Percent annual change (1982-86)	1986 (millions of dollars)	% change from '85	% of pretax profits
American Cyanamid	202.5	7	278.3	11	95.9
Dow Chemical	741.0	5	605.0	11	48.9
Du Pont	1538.0	11	1156.0	1	38.7
Ethyl	177.7	15	47.1	1	16.2
Great Lakes Chemical	26.8	12	13.2	9	30.9
Monsanto	433.0	7	523.0	11	82.2
Pennwalt	51.9	3	45.0	14	54.4
Rohn & Haas	138.0	10	132.8	8	60.6
Industry Composite	4247.5	8	3662.2	6	48.6

(Source: Business Week, June 22, 1987, pp. 144-145). See Appendix IX.

The National Agricultural Chemical Association (NACA) surveys for 1984 and 1985 reveal significant increases in R&D by as much as 39.3 percent in 1984 and 18.9 percent in 1985. We see no reason why the American agricultural chemical industry would cut back its R&D expenditures. In general, the R&D costs are usually recovered within a few years, if only because firms will not invest in products with low rates of returns.

TABLE VIII

R&D IN THE PESTICIDE INDUSTRY

	Total R&D expenditures (in billions)	Increase from previous year	Percentage increase
1985	$868.9	$138.3	18.9
1984	$730.6	$206.2	39.3
1983	$524.4		

The 1985 industry survey shows that sales in the pesticide industry (including U.S. and non-U.S. production) was $5.37 billion in 1985. Research and development, on the other hand, resulted in 25 new compounds submitted for registration in 1985, 15 in 1984 and 11 in 1983--a steady increase in new products.

Basically, the manufacturer can recover significant portions of the cost of research and development through the operation of the tax laws. In addition, the regulatory statute governing the sale and distribution of pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides significant protection to the basic manufacturer after a patent has expired. A person can distribute a pesticide if he obtains a registration from EPA. To obtain a registration, the applicant must submit test data that demonstrates that the pesticide will not cause unreasonable adverse effects to individuals or the environment. This requirement for submission of test data applies to all applicants, unlike human drugs and the proposed amendments to animal drug laws, even if the pesticide is a generic pesticide identical in all respects to a pesticide that had previously been approved by EPA.

We fully realize the importance of research and development for the pesticide industry and the need to generate new chemicals for future needs. Farmers, consumers and pesticide users depend on the development of new products to increase crop yield, protect against serious infestations and improve the quality of life for all Americans.

The current law and the 1987 proposed amendments go to great lengths to protect the investment interests of the original manufacturer, but we have done nothing to advance the interests of the farmers, ranchers, users and consumers who would benefit from greater generic competition and lower prices.

We support legislation S. 746/H.R. 2569. It is not intended to deprive basic manufacturers from recouping their R&D costs for both successful and unsuccessful products, as well as receiving an ample return on their investment.

If we combine a 17-year patent life with a five-year extension of the patent (H.R. 1345), 22 years in all, there ought to be sufficient incentive for innovation and adequate time to recoup a~~ll of the R&~~D costs.

It is time to resolve this long standing inequity.

The generic producers believe that there is a concerted effort by the brand name manufacturers to keep out competition. In the recent hearings on FIFRA, the generic producers of pesticides sought the inclusion of a reasonable standard for determining data compensation to be included in the law. The major brand name companies have consistently testified against fairness in pesticide laws and a definition of reasonable compensation. Each day that the brand name companies can prevent generic manufacturers from entering the market adds significant dollars to their bottom line at the expense of the American farmer and the American consumer. Again, the bottom line is not innovation or the need for more research and development, but corporate greed.

The same principle that gave rise to reversing the Bolar/Roche decision for the human drug industry holds true for pesticides. The need of the American farmer cannot be denied. To be competitive, we must give our farmers the best and least expensive tools with which to produce their crops.

A Compromise Solution to FIFRA:

During each of the last three congresses, the business issues of FIFRA, not the controversial environmental concerns, have generated sufficient conflict and dispute so as to frustrate the passage of the needed pesticide amendments.

We would like to see these disputes over the business issues within FIFRA resolved to the satisfaction of the basic manufacturers, the generic pesticide producers and the consumers and farmers who utilize agricultural pesticides.

We believe that S. 746 offers the best hope to resolve one of the most difficult and controversial issues of FIFRA--generic pesticide registration and data compensation. In a recent statement in the Congressional Record, Congressman Hatcher pointed out:

> "Now is the time to offer a compromise that would create generic pesticide registration and would increase competition while lowering prices for farmers and consumers. If combined with legislation such as H.R. 1345 and H.R. 2463, introduced by Congressmen George Brown, Kika de la Garza, Edward Madigan, Pat Roberts and others, it would be possible to aid basic pesticide manufacturers, generic producers and consumers. In a spirit of compromise, I offer this legislation as a means of resolving one of the most complex and controversial aspects of FIFRA legislation. IF Congress fails to act on this matter, we will be doing a great economic injustice to the American farmer.
>
> By adopting this legislation as part of a larger FIFRA amendment package, the Congress could inject a healthy dose of competition into the pesticide industry. And farmers and consumers would benefit enormously without any cost to the Government."

We share his concerns. We commend his courage.

We applaud this spirit of compromise to couple S. 746/H.R. 2569 with future patent term restoration amendments, thus achieving a unified approach that provides significant benefits to the basic manufacturers, small generic manufacturers, farmers and consumers.

It is time to give the farmer a break. It is time to lower the farmer's cost of production without taking a penny out of the federal treasury and it is time to lower pesticide prices to farmers, ranchers and consumers.

PART II: CPDA COMMENTS ON S. 1516

Although we have had limited time to review and analyze S. 1516 and have not had an opportunity to obtain a complete review by our membership, we would like to offer some comments on four concerns, including: 1) reregistration fees, 2) patent term extension, 3) the Bolar/Roche decision and 4) data compensation.

We would appreciate an opportunity to submit a supplemental statement at a later time to comment on some of the additional provisions of S. 1516.

1) Reregistration Fees:

We at CPDA are strongly opposed to the reregistration fee proposal contained in S. 1516. Such a fee proposal would increase by five times the fees contained in H.R. 2482 and S. 2792 (99th Congress) or included in H.R. 2463, introduced this year.

CPDA is composed of many small- and medium-sized businesses affected by the proposal to establish reregistration fees. This segment of the industry holds numerous pesticide registrations and is largely populated by small pesticide formulators who have their own registrations or who are subregistrants. Many of these formulators produce low-volume, low profit products that could not withstand these substantial reregistration fees. Many of these products are applied on minor use crops and are, therefore, also sold in small volumes at low profits. Many of these companies manufacture products for regional sales and distribution, and provide a unique service for regional crops.

A) Reregistration Fees and the Public Interest:

There are three statutes that require preclearance of a specific commercial product--the Federal Food, Drug and Cosmetic Act, the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act--prior to manufacture, sale and distribution of these products. In each case, the federal government acts as clearinghouse, collecting and evaluating scientific data, and ultimately registering pesticides and drugs for public use. In each case, the reregistration and preclearance of products broadly benefits the general public. Since these products and uses clearly provide a public benefit, enhancing our quality of life, stimulating new food production, and protecting public health, there should not be user fees on the registration or reregistration of pesticides.

Pesticides should not be singled out for special user fees when other preclearance statutes, such as those for drugs and animal health products, do not contain any provisions for user fees or registration or reregistration fees.

Any system of reregistration fees would, in effect, result in taxing a few to finance a regulatory system that benefits many. When government services benefit society generally, the expense of those services should be borne by the taxpayer at large, not by individuals.

The EPA reregistration process benefits the general public and the American taxpayer, not just those who produce products to be registered. These reregistration costs should be paid with public funds, not special reregistration fees.

B) The Reregistration Fee System Would Have an Adverse Economic Impact on Industry:

We would respectfully urge the Committee to evaluate the economic impact that such a bill would have on pesticide producers, formulators, and distributors that produce pest control products for agriculture and lawn and garden uses.

Many pesticide producers manufacture products for low volume sales or simply to retain the registration in the event of a potential emergency in the future. Some sale volumes equal only one or two drums. Some companies retain 300 to 400 registrations, but only 25 percent of these pesticides are self supporting. Low volume products may disappear if an unrealistic registration fee system is imposed.

Many pesticide producers manufacture products for minor uses, and generate minimal sales for these products. We can clearly see that some of these products would frankly disappear if an unrealistic reregistration fee system is imposed.

S. 1516 does not grant waivers, exemptions or adjustments to the reregistration fee schedule for minor use products. Some of these products are critically important to the American farmer and consumer, and the unavailability of certain pesticide products would make it difficult to produce certain minor food crops, especially fruits and vegetables.

Some companies hold U.S. pesticide labels because they are necessary to market certain products internationally. Many Central and South American countries will not issue a pesticide registration for internal use unless it has been registered by EPA. By the imposition of American reregistration fees, we could lose several international markets for U.S. produced products. Although these sales are frequently inconsistent and result in marginal profits, the imposition of any fees in these products would result in their cancellation, thus reducing potential exports of these formulated products.

It is important to note that the proposed reregistration fee system at EPA is but one part of an already burdensome fee structure that is rapidly expanding at the state level. It costs about $1500 for each registered pesticide product to be sold in every state. Since every pesticide must also be registered in each state before it can be sold there, pesticide producers find themselves faced with an already escalating financial burden.

The agricultural and lawn and garden pesticide business is very competitive. Many small- and medium-sized pesticide producers are able to compete in regional markets because they are able to provide a specialized product for a particular need. Many of these businesses retain many different registrations, some of which are dormant or inactive. They are retained on a standby basis so that they might be utilized as an alternative product if the Agency determined that a presently utilized product has been found to present a health concern. The company may then decide to begin production of a dormant product.

Many other products are sold on a marginal basis, with low volume sales basically covering the cost of production, marketing expenses and state registration fees. This type of pesticide provides a basic service to potential customers, and provides a business entry for the registrant. Many of these products might be used for minor use crops. With these types of registrations, companies are likely to drop the registration if the Agency decides to implement a registration fee system.

C) Small Business Considerations:

S. 1516 does not grant waivers, exemptions or adjustments to registration fees based upon public interest and economic hardships for small businesses, nor does it consider firm size and the number of registrations with EPA.

Small businesses are particularly concerned that the adoption of a reregistration fee for pesticides will discourage innovation, will limit the number of products available to distributors and will reduce the number of registrations that a pesticide producer could afford to carry in its product line.

First, the language contained in H.R. 2482, Section 3, dealing with reregistration fees, specifically notes that such a system would have based fees on distribution of market share. Second, we urge the Senate to accept the Small Business Administration's definition of small business; i.e., a business of 500 employees or less (for the chemical industry). Third, we would respectfully urge the Senate to adopt a suggestion by the Small Business Administration that fees charged to small business should be no more than 1 percent of the annual gross revenues for the pesticides for which registration action is requested. This small business cap on fees parallels the language of both House and Senate bills, H.R. 2482 and S. 2792 (99th Congress), and would establish a consistent formula for small businesses.

Although we strongly favor a small business waiver or formulators' exemption, our support for this potential waiver should not be interpreted as support for the establishment of a reregistration fee system. An adequate waiver, attached to an unacceptable regulatory policy, is still unacceptable.

D) Impact on the Farmer:

Finally, any reregistration fee would increase production costs and result in raising pesticide prices, especially for farmers, consumers, and pesticide users. This legislation has not taken into account the ripple effect this event will have on the economy. Many of our companies believe that the farmer, in many cases, will bear the brunt of these cost increases. One company offered a typical response: "The proposed fees will ultimately be passed on to the farmer. The U.S. farmers are currently facing an economic crisis and it is unlikely that they will be able to pass on this additional cost." Since generic pesticides are already cheaper on the international market (sometimes by as much as 50 to 60 percent less), the farmer could not raise his price without being further economically disadvantaged in the international marketplace. In essence, he will have to absorb these increased costs and watch his profit margin further erode or his losses mount even higher.

In most cases, the increased cost of the pesticide cannot be passed on by the farmer to the consumer of his product. It appears that farmers will be stuck for the costs of a service that benefits the entire public in the provision of a wholesome food supply, both in quality and quantity.

The pesticide producers that manufacture and distribute agricultural pesticides and pest control products for the lawn and garden are united in their opposition to the reregistration fee schedule contained in S. 1516.

2) Patent Term Extension:

Our membership at CPDA has considerable reservations about the need to extend the present patent life of agricultural chemicals by up to five years. By giving the present manufacturer an additional period of exclusive market control, it creates an anti-competitive situation that artificially inflates prices while denying market entry to generic products. The consumers--the farmer, rancher and pesticide user--will pay higher prices as a result of patent term restoration.

When the Congress enacted major drug legislation in 1984, it included three parts: 1) patent term restoration, 2) complete roll back of Bolar/Roche, and 3) generic registration. This compromise package benefitted the basic manufacturers (by getting patent extension), and generic producers were able to quickly enter the marketplace, thus stimulating competition and lowering the price of drugs for consumers. It was a well-rounded compromise that mutually benefitted industry and the consumer.

S. 1516, however, does not embrace each of these three areas. It is one-sided in that it benefits large basic manufacturers without offering lower prices to consumers or market entry for generic products. We at CPDA believe that the drug industry and the pesticide industry should be treated identically.

Despite our serious reservations about patent term extension, we would support such a proposal if it were included in a compromise package containing generic registration and a complete roll-back of the Bolar/Roche decision. We find it hard to believe that the Senate Committee on Agriculture, Nutrition and Forestry would consider only the portion of this package that keeps pesticide prices highly inflated, without seeking a way to actively reduce pesticide prices for farmers and ranchers.

We respectfully urge this Committee to adopt a comprehensive compromise package of business amendments on FIFRA that each of the three major areas--patent restoration, generic registration and a roll back of Bolar/Roche. Only then will farmers, ranchers, pesticide users and consumers get the price reductions they need and deserve.

3) Roll Back of Bolar/Roche Decision:

As we suggested earlier in our statement, we strongly favor a complete roll back of the Bolar/Roche decision.

If a product is to receive patent extension, as originally proposed by H.R. 2482 and S. 2792 (99th Congress), or as proposed in H.R. 1345, introduced by Congressmen Frederick Boucher and Michael DeWine or in S. 1516, there should be a full repeal of the Bolar/Roche decision. These legislative vehicles do not, however, contain a full repeal, but only a limited repeal for just two years. Such a limited repeal provides little benefit to generic manufacturers, especially if the testing and EPA review take five to seven years, leaving us with a three to five year deficiency. In addition, the Bolar/Roche decision does not allow the generic manufacturer to submit his test results for EPA review prior to the expiration of the patent. Congress wisely created the generic pharmaceutical industry following patent term restoration and we feel that such a move within the pesticide industry would benefit all users.

We at CPDA believe that a generic manufacturer in the pesticide industry should be on an equal footing with drug manufacturers and do the testing and file an application for registration before the expiration of a patent as long as there is a prohibition against marketing before the patent expires.

These de facto circumstances created by Bolar/Roche clearly prohibit market entry, deny small businesses access to the marketplace and deprive farmers and consumers of lower priced pesticides.

Importantly, all formulations of a pesticide containing the identical active ingredient should be considered the same pesticide and no pesticide should be subject to more than one patent extension. In no event shall more than one patent be extended for the same regulatory review period for any product.

As we stated before, we recommend inclusion of an amendment to H.R. 2463 to redress the deficiencies of the Bolar/Roche decision, as outlined in Appendix IV. If this type of amendment is not included in H.R. 2463, there is no need for patent term restoration. In effect, the basic manufacturer of the pesticide ALREADY has an extension of the patent by virtue of the time period required to replicate the test data and obtain an EPA registration prior to bringing the pesticide onto the market. Under the present circumstances, it is nearly impossible for a generic manufacturer to develop his own set of data.

4) Data Compensation:

S. 1516 includes a new procedure for fixing the amount of compensation to be paid for the use of another registrant's health and safety data for pesticides with expired patents. This provision of S. 1516 (section 204) amends section 3 (c) (1) (D) by adding a new clause (iii).

This provision in S. 1516 provides an opportunity to fix the amount of compensation through the arbitration process prior to the filing of an application for registration citing another registrant's data. The choice is clearly optional and not mandated. However laudable this goal may be, there are several inherent problems with it.

First, the arbitration process has not worked very effectively or efficiently and has become, in itself, a costly process. The present ongoing arbitration in DuPont vs. Griffin and Drexel Corporations will probably take about two years before a final decision is granted next spring (1988). In this particular case, Griffin and Drexel alone will have to spend about $750,000 on legal fees and expert witnesses.

Second, if a company selected the provision in S. 1516 to determine its cost prior to the registration of the product, it would prevent a company from filing for a registration until after the arbitration is complete. The time clock would then start to run on the registration process at EPA. As we have stated before, the delays at the Agency have been between six months to a year or more. Thus an average of at least one year would be added to the arbitration time period.

Under present law, a follow-on company may submit an application for a pesticide registration prior to the expiration of the patent, but is prohibited from marketing it until the patent expires. Thus, a company can submit a registration prior to patent expiration, have EPA completely process the application and be ready to enter the market when the patent expires. The provision in S. 1516, if implemented, would give the initial registrant an additional advantage to continue to market its product at an inflated price for up to another year or longer.

Third, under the pre-registration determination provisions of S. 1516, a company could be denied access to the marketplace during the period of arbitration (perhaps two years or longer) and EPA registration (perhaps a year or longer). Thus, sales would be prohibited for perhaps three years or more. This new three year delay represents an additional three years of de facto patent extension, since the follow-on company would not have access to the market. In fact, rather than assisting small manufacturers, formulators and distributors of "me-too" products, the proposal contained in S. 1516 actually increases the monopolistic control that the original data submitter has on the marketplace. Importantly, it also maintains higher prices for up to three or more years, forcing farmers, ranchers, users and consumers to pay more than they should.

Fourth, subparagraph (V) calls for the establishment of an unfair precedent whereby the second or third subsequent arbitration would be completely paid for by the follow-on companies. In essence, the follow-on company would have to pay the fees and expenses of the arbitrators and the attorney fees of the original data submitter. These costs could run from $500,000 to $1 million or more and could create a sufficient disincentive to entering the marketplace and banish free trade.

The second or third company may have to incur very prohibitive costs to correct the deficiencies in the original arbitration case and might want to rethink its position if it also had to pay the fees for the original data submitter. There are no "caps" on these potential expenditures and no way to control the cost or length of these proceedings.

Fifth, the fatal flaw in the amendment to section 3 (c) (1) (D) is that it does not address the main problem with data compensation--an adequate definition. No attempt is made to establish a reasonable and equitable definition of what is compensation. No attempt is made to set a clear standard for the compensation that must be paid. No attempt is made to determine if the cost of the data should be the cost of the production of the data. In effect, the amendment sidesteps the main problem with the compensation for data issue.

Sixth, this amendment also avoids the basic question--should there be compensation for data after the patent has expired? As we have previously discussed, the 1984 drug legislation allowed for generic registration after the expiration of the patent. We at CPDA believe that the drug and pesticide industries should be treated equally and fairly.

PART III

In addition to our concerns with S. 1516, we at CPDA would like to address several other FIFRA issues that concern our membership. These include:

A) Fast Track Registration for "me-too" registrations or simple amendments to existing registrations;

B) Endorsement of H.R. 2869 to coordinate and sychronize data collection among the states and EPA; and

C) State Political Subdivision under section 24 (A)

A) FAST TRACK REGISTRATION FOR "ME-TOO" PRODUCTS AND LABEL CHANGES:

We at CPDA face a difficult problem in obtaining "me-too" registrations or simple amendments to existing registrations. We are not talking about new chemicals, new uses or new efforts by the EPA to review and analyze new toxicological data. We are, however, talking about unreasonable delays in the registration process at EPA (Registration Division).

Many of these applications or amendments sit in the Registration Division of EPA in excess of a year or more. In many cases, the processing of these items could take only an hour or certainly less than a day, if the Registration Division people would process them in an expedited and timely manner. Although the backlog is not as large was it was in 1975-77, it is clearly the largest backlog in a decade and threatens to get worse, unless Congress takes decisive action.

This unnecessary backlog exists because the Registration Division at EPA is giving priority to new chemicals and new uses of existing chemicals while placing "me-too" registrations--products similar or identical to those already marketed--and label changes on a low priority. These applications simply languish at EPA and are not being processed in a timely manner.

The unnecessary backlog of "me-too" registration at EPA has an obvious economic impact on pesticide manufacturers and users. First, absent such processing by EPA, a company is denied entry into the marketplace and competition in the pesticide industry is stifled. Second, pesticide customers are frequently denied the opportunity of purchasing lower priced pesticides. Third, huge delays at EPA prevent manufacturers from planning their sales and marketing efforts, and results in some products missing their growing season. The impact is greatest on small companies with a limited assortment of products. Smaller manufacturers, formulators and distributors don't have the recourses to "ride out" long EPA delays.

We believe that it is not the intent of the Senate Committee on Agriculture, Nutrititon and Forestry to foster this unnecessary backlog at EPA and its disastrous economic effects.

We believe that the EPA needs to redirect its priorities to timely process "me-too" applications and amendments to existing registrations and needs Congressional assistance to accomplish this change in direction. The Agency needs to re-establish its priorities to properly process these registrations within specifically defineable timetables. As part of its reassessment of the present registration system, the Agency should assign some of its registration personnel to the administration of the whole registration process, including me-too registrations and amendments. If necessary, the administration should be directed to transfer personnel from other programs so as to ensure that pesticides are timely registered.

We at CPDA would favor an amendment to Section 3 (c) (3) that would require the Administrator to:

1) Achieve the registration of all pesticides in the most expeditious manner practicable;

2) Establish a registration priority to applications for a product that is identical or substantially similar in composition to any currently registered pesticide or for an amendment to existing registrations;

3) Notify the registrants within 45 days after receiving an application to determine if it is complete;

4) Notify the registrants within 90 days after receiving a completed application if it has been granted or denied; and

5) Notify the registrants in written form of the specific reasons for denial of registration.

We have included a suggested amendment to accomplish this reordering of EPA's priorities.

B) COORDINATION AND SYNCHRONIZATION OF PESTICIDE DATA REQUIREMENTS AMONG STATES AND EPA:

We at CPDA strongly support H.R. 2869, the Pesticide Data Coordination and Sychronization Act of 1987, introduced by Congressmen Steve Gunderson (R-Wisc.) and Pat Roberts (R-Kan.).

In 1984, California passed S.B. 950 to require the filling of pesticide data gaps. To implement this law, the State adopted a definition of a "data gap," created a list of tests that need to be completed, and established a detailed timetable for filling these data gaps. The State, however, did not take into consideration the attempt of the Congress to create their own reregistration timetables in H.R. 2482 and S. 2742 (99th Congress) or H.R. 2463 (100th Congress) to fill these same data gaps. This is a new and growing problem. Several states are now considering such legislation and Arizona has just this year passed its new law.

"In essence," remarked Steve Gunderson (R-Wisc.) (Congressional Record, July 1, 1987, E 2740), "in attempting to establish their own expedited reregistration programs to fill data gaps, the states actually will establish agendas and timetables which will duplicate and even conflict with the federal requirements."

"...It is critical," concluded Gunderson, "that data requirements among the states and EPA be coordinated and synchronized so that only one set of data needs to be generated within the same timeframe." "Unnecessary, repetitive and redundant testing only consumes valuable time and resources, but also delays the closing of data gaps," he noted. "Valuable time and resources which could be used to develop new data are wasted in refocusing on gaps that have already been or are in the progress of being filled."

H.R. 2869 will help reduce the cost of pesticides, eliminate duplicative and unnecessary testing, expedite the closing of data gaps and make sure that pesticides for farmers and consumers, expecially minor use products, will be available whereever needed.

C) STATE POLITICAL SUBDIVISIONS SHOULD NOT REGULATE SALE AND USE OF PESTICIDES:

We at CPDA strongly oppose S. 1524, the Authority of Local Governments Under FIFRA, introduced by Senators John Chafee (R-R.I.), David Durenberger (R-Minn.) and Robert Stafford (R-Ver.) on July 22, 1987. We support the decision of the U.S. Court of Appeals for the Fourth Circuit when it ruled on June 16, 1987, in the case of the Maryland Pest Control Association versus Montgomery County, Maryland, that FIFRA preempts and invalidates local action to regulate the sale and use of pesticides. We respectfully urge that S. 1524 not be included in any package of FIFRA amendments considered by this Committee.

Under Section 24 (A) of FIFRA, Congress extended limited pesticide authority to the states to regulate the sale and use of pesticides. The legislative history clearly demonstrates that Congress did not want to share its authority with local jurisdictions.

When the Senate Committee on Agriculture passed its FIFRA bill in 1972, its accompanying committee report concluded:

> The Senate Agriculture Committee considered the decision by the House Committee to deprive political subdivisions of states and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty states and the federal government provide sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any, local authorities, whether towns, counties, villages or municipalities, have the financial wherewithal to provide necessary expert regulation comparable with that provided by the state and federal governments. On that basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the states, should be understood as depriving such local authorities and political subdivisons of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, P. 4008 (1972).

At about the same time, the Senate specifically rejected an amendment that would have allowed local political subdivisions, such as cities, towns, counties, etc., to regulate the sale and use of pesticides. The vote was 71-0.

Despite this explicit legislative history, there have been, during the 1980s, many political subdivisons of a state that have attempted to exercise regulatory authority.

Local jurisdictions have been enacting restrictions on pesticides that create considerable hardships on farmers, ranchers, foresters, homeowners, pesticide users and manufacturers. These jurisdictions are, in effect, denying the pesticide user--and the public--the benefits of pest control.

We oppose granting local political subdivisons the authority to regulate the sale and use of pesticides for the following reasons: First, local jurisdictions simply are not equipped to make the scientific and regulatory decisions required to validly regulate pesticides. When regulations are based on fear, hysteria and other unscientific grounds, the resulting loss of benefits is unwarranted. Second, we question the need for local jurisdictions to regulate pesticides. What risk uncontemplated by EPA or the State Agency does the local community want to protect against? What risk goes unprotected except for local notification ordinances? And what is the magnitude of that risk? Have EPA and the states been negligent in not identifying and reducing this risk? Third, we believe that the legislative history is clearly written to explicitly reject local regulation of pesticides. Fourth, we oppose local jurisdictions regulating the notification of use of pesticides in both urban and rural settings. These regulations should be established at the state level.

Notification can take many forms. One county in a New England state contemplated a "notification" regulation which would have required persons dusting their roses to notify everyone within a half of a mile before doing so. Does notification include prior notification, post notification, personal notification, or notification by pubication? Then the question arises as to who is to be notified: those immediately adjacent or everyone within a certain radius? Consider, for example, an apartment dweller wishing to spray for any common pest; who must that person notify?

The broad definition of pesticide adds to the potential breadth and confusion. It could require people to post a notice if they sprayed for household insects, applied a disinfectant in the bathroom, dusted roses, or put chlorine in a swimming pool.

Commercial establishments using cleansers and other cleaning solvents which are pesticides might need to post continuously.

We at CPDA favor an amendment to Section 24 (A) of FIFRA to prevent local jurisdictions from regulating the sale and use of pesticides. With this amendment included, Section 24 (A) would read as follows: "A State, but no political subdivision of a state may regulate the sale and use of any federally registered pesticide..."

CONCLUSION:

We at CPDA greatly appreciate the opportunity to testify before this committee and look forward to working with you to help resolve some of the complex and controversial aspects of amendments to FIFRA.

Thank you.

(Appendix I-Appendix IX follow:)

Appendix I

EXHIBIT 1

THE SECRETARY OF
HEALTH AND HUMAN SERVICES,
Washington, DC, March 10, 1986.

Hon. STROM THURMOND,
Chairman, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: There is pending before the Committee, S. 1093, a bill "To amend the patent law to restore the term of the patent in the case of certain products for the time of the regulatory review period preventing the marketing of the product claimed in the patent." We take this opportunity to inform you of our views on that bill. We understand that S. 1093 is scheduled for mark-up on March 11, 1986 before the Subcommittee on Patents, Copyrights and Trademarks.

Our views focus on S. 1093 as it would affect veterinary drugs, which are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic (FDC) Act. S. 1093 would authorize the restoration of patent time lost due to Federal premarket requirements for veterinary drugs, pesticides, and agricultural chemicals.

In summary, we support patent restoration for veterinary drugs, but urge the Committee to add an additional provision that would enable manufacturers to obtain Federal premarket approval to market generic versions of these drugs without having to duplicate the potentially costly and time-consuming safety and effectiveness studies that are required of pioneer manufacturers. Without such a provision, there would appear to be no need for patent restoration since the current Federal requirement for duplicative testing would continue to serve as an effective economic barrier to competition even after the expiration of patents that would be restored by this legislation.

The Department of Health and Human Services traditionally has supported patent restoration for the products that require the premarket approval of FDA. These products often entail high development costs, the risk of failure and small potential markets. In addition, innovators typically lose years of patent exclusivity because of testing requirements and regulatory review. We are mindful of the paradox that the careful and time-consuming scientific review needed to confirm safety and effectiveness may be reducing initiatives to develop new veterinary drugs. Streamlining the regulatory process will help. However, the FDA premarket approval system must continue to be thorough enough to assure safety and efficacy even if that means living with a process that takes longer than we would ideally prefer. We want to encourage innovation, but not at the expense of safety. Consequently, we support patent extension for veterinary drugs as a means of encouraging innovative research.

Patent restoration would have little meaning, however, if Federal regulatory barriers had the effect of preventing the marketing of virtually identical generic products after patents expire. Such a situation existed for human drugs until 1984, when the Congress enacted legislation that both extended patents associated with human drugs and removed regulatory barriers that effectively prevented the development of many generic human drugs. The situation still exists, however, for veterinary drugs.

Consequently, in addtion to patent extension, we strongly support the enactement of an explicit statutory authority that would allow a manufacturer to market a generic version of a veterinary drug without having to duplicate the time-consuming and costly studies that are necessary to demonstrate that the original version of the drug is safe and effective. The generic manufacturer only would have to demonstrate in an "abbreviated" application for marketing approval to FDA that it is capable of manufacturing an equivalent product.

FDA presently allows abbreviated applications for generic versions of veterinary drugs that were approved before 1962, the year in which Congress amended the FDC Act to require that both human and veterinary drugs be shown to be effective as well as safe. A similar procedure has not been established for post-1962 veterinary drugs. As a consequence, the duplicative testing for safety and effectiveness that generic manufacters must conduct for post-1962 drugs constitutes an effective economic barrier to their development. In this respect, the Federal drug approval process unwittingly serves as a quasi-patent whose term never expires.

We have concluded, therefore, that both patent restoration and an abbreviated approval procedure ought to be included in the same legislation so that they may be considered and, hopefully, enacted together. We continue to belive that it is good public policy to link the two concepts in order to foster research for new products and at the same time encourage competition and lower prices. In our view, it would be unfair to consumers as well as to the industry as a whole if one were enacted but not the other or if a substantial time lag occured between the enactment of both. We would be pleased to work with the Committee to add an abbreviated application provision to S. 1093.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program

Sincerely,

OTIS BOWEN,
Secretary.

Appendix II

PESTICIDES AND THE COST OF PRODUCTION: POTENTIAL FARM SAVINGS OF H.R. 2569/S. 746

Crop*	1985 cost of chemicals per acre***	1985 chemical percentage of cash variable expenses	Savings per acre if prices drop 20 % due to generic competition
Corn	$17.58	8.6%	$3.52
Sorghum	8.52	13.4%	1.70
Barley	5.43	10.4%	1.09
Oats	1.11	.3%	.22
Wheat-all	2.93	5.9%	.59
Spring wheat	5.09	12.5%	1.02
Durum wheat	5.35	14.2%	1.07
White wheat	9.58	12.9%	1.92
Winter wheat	1.50	3.3%	.30
Rice	26.88	10.8%	5.38
Soybeans	17.47	32.3%	3.50
Sunflower	13.30	27.3%	2.66
Peanuts-all	79.63	29.3%	15.93
" southeast	94.58	33.0%	18.92
" VA & NC	88.76	28.7%	17.75
Flax	4.15	13.6%	.83
Cotton-all	45.18	20.5%	9.04
" Delta	72.27	32.3%	14.45
" southeast	96.04	35.7%	19.21
Sugar beets	44.57	15.3%	8.91
" TX & NM	101.13	22.9%	20.21
Sugar cane	56.44	7.5%	11.29
" Hawaii	125.64	4.8%	25.13
Tobacco**			
" burley	$70.08	3.6%	$14.02
" flue-cured	94.44	4.6%	18.89

* Economic Indicators of the Farm Sector, Costs of Production, 1985 (United States Department of Agriculture, Economic Research Service), ECIFS 5-1.

** Annette Clausen, Economic Research Service, USDA.

*** Chemical category does not include fertilizers

Appendix III

Potential savings from 20 percent price reduction in pesticide prices (based on 1986 planted acreage)

State	Corn
Alabama	$1.20
Arkansas	$0.32
California	$1.76
Colorado	$2.89
Florida	$0.70
Georgia	$3.17
Idaho	$0.46
Illinois	$37.31
Indiana	$20.59
Iowa	$43.30
Kansas	$5.10
Kentucky	$6.09
Louisiana	$1.41
Michigan	$9.86
Minnesota	$22.53
Mississippi	$0.74
Missouri	$8.98
Montana	$0.28
Nebraska	$25.70
North Carolina	$5.63
North Dakota	$3.10
Ohio	$13.73
Oklahoma	$0.25
Oregon	$0.21
South Carolina	$1.94
South Dakota	$11.62
Tennessee	$3.20
Texas	$4.91
Vermont	$0.36
Virginia	$2.57
Washington	$0.60
West Virginia	$0.33
Wisconsin	$13.73
Total U.S.	$269.89

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) section 1814(a)(2)(D) of the Social Security Act is amended by inserting ", occupational," immediately after "physical".

(b) Section 1835(a)(2)(A)(i) of such Act is amended by inserting ", occupational," immediately after "physical".

(c) Section 1835(a)(2) of such Act is further amended—

(1) by striking out "and" at the end of subparagraphs (B) and (C);

(2) by striking out the period at the end of subparagraph (D) and inserting in lieu thereof "; and "; and

(3) by adding after subparagraph (D) the following new subparagraph:

"(E) in the case of outpatient occupational therapy services, (i) such services are or were required because the individual needed occupational therapy services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.".

(d) The last sentence of section 1864(p) of such Act is amended by inserting "and occupational therapy services" after "speech pathology services".

Sec. 2. The amendments made by the first section of this Act shall be applicable in the case of services furnished on and after the first day of the first month which begins not less than thirty days after the date of the enactment of this Act.

FIFRA, "EXCLUSIVE USE," AND JUSTICE DEPARTMENT OPINION

HON. FLOYD J. FITHIAN

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Monday, October 31, 1977

Mr. FITHIAN. Mr. Speaker, today, we are considering amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). One of the most important aspects of this legislation is the implementation of a 5-year period of "exclusive use of data," in which the company or pesticide registrant would have sole proprietary use of that data. Although I would have preferred a mandatory licensing system with compensation spread over nearly 10 years, I supported this effort in the spirit of compromise so that the legislative process could be expedited.

In my view, this provision of the FIFRA amendments is very generous to the manufacturers of technical grade pesticides—generous perhaps to a flaw. It should be a continuing responsibility of the House Agriculture Committee to assure that our action today does not exacerbate the growing tendency toward oligopoly in the pesticide manufacturing industry.

The Department of Justice, in two letters to me, clearly have stated their objections to the "exclusive use of data," pointing out that it would be harmful to competition in the pesticide industry. If the FIFRA amendment proposed today do not reverse this trend, the Congress will have an obligation to return to this legislation with further corrective action. And this action might be necessary.

For the benefit [illegible] my colleagues in the House, I am inserting the two letters from the Department of Justice in the RECORD.

WASHINGTON, D.C.,
September 6, 1977.

Hon. FLOYD J. FITHIAN,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN FITHIAN: This is in response to the request of your staff for the views of the Department of Justice on the so-called "industry compromise" presented by the National Agricultural Chemicals Association ("NACA") regarding the trade secret and data compensation provisions in the Federal Insecticide, Fungicide, and Rodenticide Act.

As we have previously indicated in response to other inquiries, we find the NACA proposal to be unacceptable. The NACA proposal basically relies upon an "exclusive use of data" concept. While it may be true that use of data and patent rights are technically distinguishable, as NACA argues, we think it equally true that both entail potential monoply and monopoly profits, and we adhere to our expressed views that exclusive use of data may be, for all practical purposes, an extension of a patent monopoly. Thus, we continue to oppose exclusive use of data, in the belief that its impact on the industry (and on consumers) would likely be comparable to the impact of the Act as discussed in the recent EPA report.

We would not attempt to predict the likely impact of NACA's limited data sharing proposal, to take effect in the event of additional data requirements, and in particular of the fall-back "equal" cost sharing concept. In any event, this concept appears to exclude new registrants.

In summary, we adhere to the views we have previously expressed. We also believe that Congress should keep in mind that a "compromise" among some segment of affected industries is not necessarily in the interest of the public.

Sincerely,

PATRICIA M. WALD,
Assistant Attorney General.

WASHINGTON, D.C.,
April 27, 1977.

Hon. FLOYD J. FITHIAN,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN FITHIAN: This is in response to your letter of April 22, 1977, concerning the competitive effects of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a key area of concern to you and your colleagues as you consider proposed amendments to the Act. You ask for our evaluation of the "climate for competition" under present law, and enclose a copy of the recent EPA Report, "FIFRA, Impact on the Industry." You also ask for any comments we may have on conflicting proposals to resolve competitive issues.

The Antitrust Division prepared comments for the Agriculture Committee concerning aspects of FIFRA in a letter responding to an inquiry by Representative James P. Johnson. These comments were made part of the record of the oversight hearings on March 7. A copy of that letter is attached.

The Department of Justice supports the EPA's evaluation and conclusions with respect to the direct and indirect anticompetitive effects of the trade secret provisions of Section 10 of FIFRA.[1] We concur with EPA that some expression of Congressional intent would be desirable to support the Agency's position on the issues relating to competition in the pesticide industry.

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[1] See pages 6, 9, 10, 11, 20-22 of the EPA Report.

It should be noted that the EPA raises two separate issues: (1) the access to or reliance upon safety, efficacy, environmental chemistry data ("test data"), without actual disclosure, which has been furnished to EPA by developers, and (2) the public disclosure of such data. The Department believes that the competitive issues hinge principally on the ability of applicants to use such test data to satisfy registration requirements.

However, we feel that the EPA report has not fully explored all of the competitive issues, and we are opposed to certain recommendations made to EPA, as outlined in the Appendix to its Report.

1. Data Disclosure and Trade Secret Exemption. The EPA report examines the impact of the data licensing, public access, and trade secret provisions (§§3(c)(1)(D), 3(c) (2) and 10) of FIFRA[2] upon competition in the pesticide industry. The conflict between sections 3(c)(1)(D) and 10 has generated much of the controversy surrounding FIFRA. Ten suits have been filed in various federal courts to prevent the EPA from disclosing data which the data producing firms (i.e., developers)[3] claim are trade secrets and thus nondisclosable under § 10. Representative Johnson's request for the Antitrust Division's comments on FIFRA was prompted by a complaint that one major data producing firm was using the § 10 trade secret exemption to extend its patent monopoly past the expiration of its patents.

The Antitrust Division's letter to Mr. Johnson delineates its views concerning sections 3(c)(1)(D) and 10. The Division's letter concludes that the scope of the trade secret provisions of FIFRA may have been improperly extended in denying potential competitors access to test data prepared by developers. We agree with the position of EPA that "trade secret status should be routinely extended only to truly secret information concerning manufacturing processes (and, perhaps, to the list of deliberately-added inert ingredients in formulated, end-use products."[4]

2. *Extension of Patent Protection*. The data producing firms have argued that the generation and compilation of data necessary to register a new pesticide appreciably diminishes the duration of patent protection from the statutory 17-year period to about 12 years. This justifies, it is suggested, the broad interpretation of section 10: an effective extension of the patent period is necessary to make up for the time lost developing the data, and claiming trade secret status for all data provides that extension. A separate but related argument is that availability of the data (whether by opening the files, or by disclosure, or by allowing referencing of the data without actual disclosure) is a disincentive to development of new pesticides; therefore, disclosure is at the expense of research and development directed toward new and innovative pesticides. These considerations may be the basis for a recommendation to EPA (see Appendix of EPA Report, at 29) to lengthen patent protection, as one of several possible actions that would allegedly foster pest control research and development.

We find both industry arguments unconvincing. The former ignores the fact that patents of this nature are typically pending for several years before the patent is granted (when the period of protection begins to run), thus giving the patent owner considerable time to conduct testing necessary for registration. The latter is contrary to actual experience. The pesticide industry existed from 1947 through 1972 without any legislation protecting the confidentiality of registration data—a period during which the USDA and its successor, the EPA, freely and openly referred to all data in connection with applications for registration of pesticidal formulations similar to those previously registered. If there was a disincentive toward research and development, it did not manifest itself in any decline in new pesticide registrations. It is curious that the asserted need for protection of test data became evident only when significant numbers of pesticide patents began to run out. We find the disincentive argument somewhat disingenious.

We also find the extension of patent protection inconsistent with long-standing law accommodating the patent laws with our system of free competition. The courts have held that the patent grant, as an exception to the competitive system's general prohibition of monopolies, must be strictly confined to its boundaries. Attempts to extend the scope or duration of patent monopoly have been routinely struck down. See, e.g., *Brulotte v. Thys Co.*, 379 U.S. 29 (1964) (post-expiration royalties not permitted); *Hartford Empire Co. v. United States*, 323 U.S. 386 (1945) (pooling of patents to effect monopoly control of entire industry illegal). Any proposal having the effect of extending the patent protection beyond the statutory period would be inconsistent with existing law and with the spirit of free competition. Furthermore, since the inception of our patent laws, Congress has provided a single period of patent protection for all industries. We see no reason for a special exception for the pesticide industry.

3. Compensation. Section 3(c)(1)(D) requires that applicants compensate, or offer to compensate, owners of test data for use of data in processing their applications for registration. The use of compensation is not discussed at length in the EPA Report, perhaps because problems in determining what data is available for referencing have been so formidable that the issue of availability and compensation has not arisen frequently.

There are several considerations which bear on the issue of compensation for the use of test data. Patent owning, data producing firms may be amply compensated during the 15 to 17 year period in which they can exact monopoly prices from consumers. Prior to the 1972 FIFRA amendments, when generic producers could economically manufacture technical pesticides upon expiration of the patent, prices typically dropped dramatically upon patent expiration. For example, the price per pound of DDT fell to about ⅙ of the pre-expiration price when competition was introduced, suggesting that monopoly profits were quite significant (and likely adequate to cover registration costs).

We think it should also be kept in mind that the compensation provisions could be used to effect anticompetitive ends in dealing with both competing manufacturers of technical pesticides and formulators of end-use products from the technical materials. There are inherent problems in determining what constitutes "reasonable" compensation for data. Thus, the provision could provide a tool for extending patent monopoly by pricing data out of reach of small competing manufacturers and for exercising control of the end-use and/or end-users after initial sale of the patented material.[5] We consider both types of action inconsistent with competitive policy.[6]

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[2] For description of these provisions, see attachment, pp. 2-5.

[3] This term is used to identify firms that have produced data to support registration. These firms are generally large, R&D-oriented companies.

[4] See page 11 of EPA Report.

[5] See ¶ 4, *infra*.

[6] On February 23, 1977, the Department of Justice filed a proposed consent decree that would settle an antitrust action brought against Union Carbide charging restraint on resale and use of its technical pesticide carbaryl. The consent decree requires Union Carbide to assist formulators in obtaining registrations by making data available for EPA use. Union Carbide is also prohibited from collecting compensation for any data that has been used free of charge by another applicant. This free licensing provides an important precedent.

We also note that Union Carbide typically did not charge any fee for its vendees' use of its data on file with the EPA. Apparently Carbide saw no disincentive in the access to its data.

Finally, there is a serious question as to the appropriateness of requiring formulators to compensate developers for the use of test data, a cost which could be reflected in the price of technical-grade chemicals purchased from the developers. We agree with EPA that primary data compensation should be limited to "registrants of technical, rather than end-use products."[7]

4. Vertical Effects. The area of horizontal competition between manufacturers is the primary focus of the EPA report. However, FIFRA also provides a mechanism for control of certain vertical aspects of distribution of formulations of the technical material. FIFRA currently requires that each formulation of a pesticide be registered by each firm that distributes the formulation. Thus, if Firm A, the patent owner and producer of data for pesticide X, sells the technical form of X to Firm B, which desires to make a 50 percent concentration of X for use on soybeans, Firm B must obtain a registration for its 50 perecnt formulation. The majority of the data that Firm B would be required to provide relates to the technical form of X and would have been submitted to the EPA by Firm A when it registered X. If Firm B has Firm A's permission, it can reference this data and will need to provide only relatively inexpensive efficacy data relating to the particular concentration, target pests and protected crops. If, as is frequently the case, Firm A also markets a 50 percent formulation for use on soybeans, Firm B may incur no major expense at all in registering its formulation.

However, control over data by Firm A may allow it to control use of pesticide X by Firm B (perhaps exercised by insisting that Firm B market X only in certain formulations in which Firm A has no interest). Firm A may also use its control of data to attempt to limit resale of pesticide X to other firms. Thus, limits on availability of data can have serious anticompetitive effects in a vertical sense.

Rejection of the broad definition of trade secrets urged by the data producing firms would make most data available without the need for permission from the data producing firm. Elimination of the compensation requirement would further diminish the risk of vertical restraints, but a reasonable compensation provision that eliminates uncertainty as to price and is inapplicable to formulators would be inconsistent with antitrust principles.

5. Product Leverage. In its discussion of advantages which the patent owner enjoys over potential manufacturers upon expiration of a patent, the EPA report neglects one substantial advantage. The patent owner is, as the report suggests, likely to be a large chemical firm that may sell, in addition to its once-patented pesticide, a variety of pesticidal products (or other chemical products) through a distribution channel of independent formulators. A distributor might be dissuaded from purchasing the once-patented pesticide from a new, cheaper supplier by the risk of losing the broader product line offered by the original manufacturer. If this "product line leverage" rises to threats or requirements that the distributor continue to purchase the now unpatented pesticide or lose the full product line the antitrust laws may have been violated.

6. Impact of Reregistration. The reregistration process has a potentially destructive effect upon existing competition in the manufacture of technical pesticides. Prior to enactment of the 1972 amendments, several generic manufacturers obtained registrations on technical grade pesticides where patents had expired and began to manufacture and market those pesticides. Registrations were obtained without submitting any support data. When these pesticides are called in for reregistration, however, each registration will have to be supported by adequate test data. Because practically all such data was submitted prior to 1970, compensation is not a barrier to continued competition, but availability of the data (through reference or disclosure) is a problem. (The data producing firms' position on trade secrets, if adopted by Congress, could eliminate what little competition does exist in the manufacture of technical grade pesticides.)

7. Data on Impurity Standards. The debate on impurity standards may be a forerunner of other similar problems in data referencing. We understand that at least one of the major data producing firms is prepared to assert that EPA may not use the firm's technical pesticide formula for comparison when registering a "me too" firm's version of the pesticide upon expiration of the patent. Thus, even if the "me too" manufacturer could properly reference all the required data, the original manufacture could prevent registration by prohibiting EPA from comparing the two technical formulae to determine whether the "me too" manufacturer's product contains more or different impurities.

8. Conclusion. The EPA report very adequately addresses the major competitive impasse in FIFRA—the interplay between sections 3(c)(1)(D) and 10. The Department of Justice would strongly oppose any attempt to resolve the problems by expanding patent protection through either lengthening the duration of patent protection or adoption of the broad definition of trade secrets urged by the data producing firms.

We understand that many of the problems discussed above are addressed in amendments to FIFRA being proposed by EPA. We hope our views will be of assistance to the Subcommittee in its consideration of the competitive issues presented by FIFRA.

Sincerely yours,

DONALD I. BAKER,
Assistant Attorney General,
Antitrust Division.

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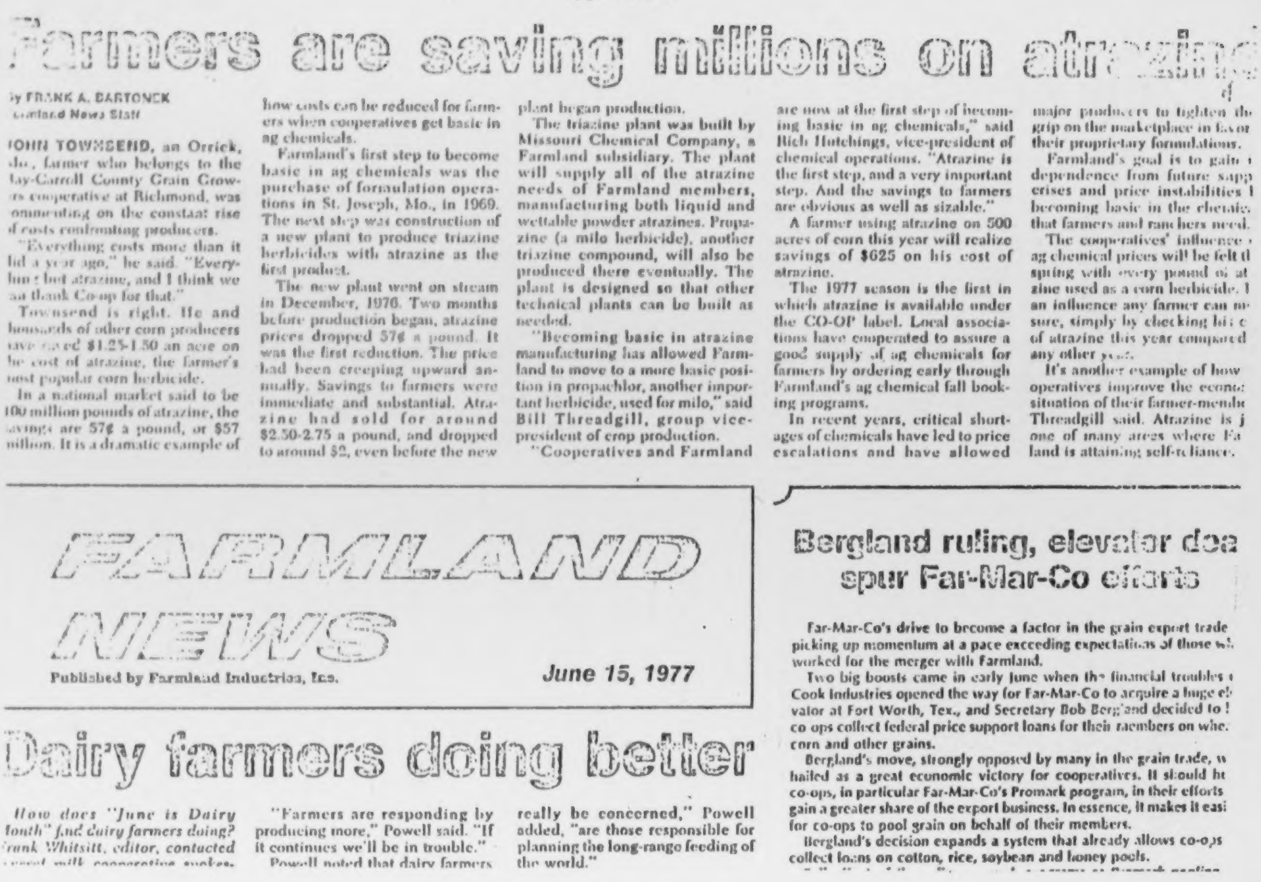
[7] See EPA Report at 20.

Appendix V



Farmers are saving millions on atrazin

y FRANK A. BARTONEK
armland News Staff

OHN TOWNSEND, an Orrick, lo., farmer who belongs to the ay-Carroll County Grain Grow-rs cooperative at Richmond, was ommenting on the constant rise f costs confronting producers.

"Everything costs more than it lid a year ago," he said. "Every-hing but atrazine, and I think we an thank Co-op for that."

Townsend is right. He and housands of other corn producers ave saved $1.25-1.50 an acre on he cost of atrazine, the farmer's ost popular corn herbicide.

In a national market said to be 100 million pounds of atrazine, the avings are 57¢ a pound, or $57 million. It is a dramatic example of how costs can be reduced for farmers when cooperatives get basic in ag chemicals.

Farmland's first step to become basic in ag chemicals was the purchase of formulation operations in St. Joseph, Mo., in 1969. The next step was construction of a new plant to produce triazine herbicides with atrazine as the first product.

The new plant went on stream in December, 1976. Two months before production began, atrazine prices dropped 57¢ a pound. It was the first reduction. The price had been creeping upward annually. Savings to farmers were immediate and substantial. Atrazine had sold for around $2.50-2.75 a pound, and dropped to around $2, even before the new plant began production.

The triazine plant was built by Missouri Chemical Company, a Farmland subsidiary. The plant will supply all of the atrazine needs of Farmland members, manufacturing both liquid and wettable powder atrazines. Propazine (a milo herbicide), another triazine compound, will also be produced there eventually. The plant is designed so that other technical plants can be built as needed.

"Becoming basic in atrazine manufacturing has allowed Farmland to move to a more basic position in propachlor, another important herbicide, used for milo," said Bill Threadgill, group vice-president of crop production.

"Cooperatives and Farmland are now at the first step of becoming basic in ag chemicals," said Rich Hutchings, vice-president of chemical operations. "Atrazine is the first step, and a very important step. And the savings to farmers are obvious as well as sizable."

A farmer using atrazine on 500 acres of corn this year will realize savings of $625 on his cost of atrazine.

The 1977 season is the first in which atrazine is available under the CO-OP label. Local associations have cooperated to assure a good supply of ag chemicals for farmers by ordering early through Farmland's ag chemical fall booking programs.

In recent years, critical shortages of chemicals have led to price escalations and have allowed major producers to tighten th grip on the marketplace in favor their proprietary formulations.

Farmland's goal is to gain dependence from future supp crises and price instabilities becoming basic in the chemic that farmers and ranchers need.

The cooperatives' influence ag chemical prices will be felt t spring with every pound of at zine used as a corn herbicide. an influence any farmer can m sure, simply by checking hi of atrazine this year compared any other year.

It's another example of how operatives improve the econo situation of their farmer-memb Threadgill said. Atrazine is j one of many areas where Fa land is attaining self-reliance.

FARMLAND NEWS
Published by Farmland Industries, Inc.
June 15, 1977

Dairy farmers doing better

How does "June is Dairy onth" find dairy farmers doing? rank Whitsitt, editor, contacted

"Farmers are responding by producing more," Powell said. "If it continues we'll be in trouble."

Powell noted that dairy farmers really be concerned," Powell added, "are those responsible for planning the long-range feeding of the world."

Bergland ruling, elevator dea spur Far-Mar-Co efforts

Far-Mar-Co's drive to become a factor in the grain export trade picking up momentum at a pace exceeding expectations of those w worked for the merger with Farmland.

Two big boosts came in early June when the financial troubles Cook Industries opened the way for Far-Mar-Co to acquire a huge el vator at Fort Worth, Tex., and Secretary Bob Bergland decided to co ops collect federal price support loans for their members on whe corn and other grains.

Bergland's move, strongly opposed by many in the grain trade, w hailed as a great economic victory for cooperatives. It should he co-ops, in particular Far-Mar-Co's Promark program, in their efforts gain a greater share of the export business. In essence, it makes it easi for co-ops to pool grain on behalf of their members.

Bergland's decision expands a system that already allows co-ops collect loans on cotton, rice, soybean and honey pools.

Appendix VI

PATENT TERM EXTENSION AMENDMENT

Same as 1986 House and Senate passed bills (i.e., up to a 5 year patent extension to compensate for regulatory delays, 3 years if the review period began before enactment of the bill, none if regulatory review completed by enactment) except that there is no termination date for the amendment and except for inclusion of a provision to reverse the holding of the court in Roche Products v. Bolar Pharmaceutical Co. Inc. as follows:

Section 271(e) of title 35, United States Code, is amended by--

(1) redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively;

(2) adding a new paragraph (3) as follows:

"(3)(A) During the term of a patent relating to a pesticide (including a patent which claims a pesticide, a method for using a pesticide, or a method of manufacturing a pesticide) which is or has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act or which is marketed with the permission of the holder of such patent, it shall not be an act of infringement of such patent to make, use, or sell such pesticide solely for testing reasonably related to the development and submission of data-

"(i) to meet regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act,

"(ii) to obtain a tolerance or an exemption from a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act, or

"(iii) to obtain a food additive regulation or an exemption from a food additive regulation under section 409 of the Federal Food, Drug, and Cosmetic Act.

(B) It shall be an act of infringement for any person to submit any application under the Federal Insecticide, Fungicide, and Rodenticide Act or section 408 or 409 of the Federal Food, Drug, and Cosmetic Act for a pesticide covered by a composition of matter patent, method of use patent, or method of manufacturing patent issued for the pesticide if the purpose of the submission of such application is to obtain approval of such application to engage in the commercial manufacturing, use, or sale of a pesticide covered by such patent before the expiration of such patent, unless such person is the holder of such patent or a licensee of the holder.

(C) For purposes of this paragraph, all formulations of a pesticide containing the identical active ingredient shall be considered the same pesticide.";

(3) amending paragraph (4), as redesignated, by inserting "or paragraph (3)(A)" after "paragraph (1)"; and

(4) amending paragraph (5), as redesignated, by--

(A) inserting "and paragraph (3)(B)" after "paragraph (2)", wherever it appears in such paragraph; and

(B) inserting "or pesticide" after "drug" wherever it appears in such paragraph.

Appendix VII

The Committee for Research and Development of Agricultural Chemicals
1627 K Street NW
Suite 500
Washington, D.C. 20006
202 956 5200

FIFRA FACT SHEET

Agrichemical Industry at a Glance

Total domestic U.S. sales for pesticides were $4.06 billion in 1985, down 9 percent from $4.46 billion in 1984. Total U.S. herbicide sales in 1985 were $2.6 billion and insecticide sales were $968 million. Total U.S. fungicide sales were $269 million in 1985. (Source: 1985 Industry Summary for reporting companies from the National Agricultural Chemicals Association (NACA).)

The industry employs about 95,000 in manufacturing, research and development, distribution and sales in the U.S. The products are used in all 50 states by several million farmers, ranchers and applicators.

Major applications of pesticides are for such crops as corn, wheat, soybeans, rice and cotton. Smaller applications by volume, but no less important to the farmers that use them, are for fruit and vegetable crops such as peaches, apples, carrots, cherries, avocados, tomatoes, peanuts and pecans.

From Research to Market

In 1985, of the 26 innovative companies reporting, a total of 185,013 compounds were researched and brought to a screening process. This process determines which compounds are likely to show some scientific or market potential. Then the compounds are submitted to long-term "feeding" or application tests.

The elapsed time from first discovery, through long-term feeding studies, to submission for first commercial registration for a product takes an average of 89 months or just over seven years. In 1985, this process resulted in a total of three new compounds receiving their first full registrations.

From the submission of the registration package until the granting of registration to market means an additional two years before a product can be marketed.

1985 research and development (R&D) expenditures for new products were $553 million or 67 percent of the total R&D costs for the industry.

Appendix VIII

U.S. Pharmaceutical Industry Sales & R&D Expenditures, 1961-1986[a] (millions of dollars)

1

Year	U.S. Sales[b]	Global Sales and R&D-PMA Member Firms		
		Sales Human and Veterinary[c]		R&D[d]
	Human Dosage	*Dosage Only*	*Dosage & Bulk*	*Human & Veterinary*
1986[e]	24,774	34,567	36,064	4,647
1985	22,065	30,698	32,026	4,078
1984	19,345	28,615	29,854	3,579
1983	17,278	26,254	27,506	3,218
1982	15,394	24,466	25,654	2,774
1981	13,000	22,378	23,530	2,340
1980	11,799	21,460	22,513	1,977[f]
1979	10,044	17,789	18,939	1,627
1978	9,156	15,463	16,431	1,404
1977	8,233	13,377	14,155	1,276
1976	7,669	12,295	13,035	1,164
1975	6,895	11,129	11,769	1,062
1974	6,083	9,755	10,361	942
1973	5,507	8,403	8,839	825
1972	5,018	7,576	7,930	726
1971	4,667	6,787	7,605	684
1970	4,322	6,226	6,637	619
1969	4,008	5,632	6,008	550
1968	3,655	5,097	5,482	495
1967	3,226	4,546	4,941	461
1966	3,011	4,105	4,509	416
1965	2,779	3,758	4,136	365
1964	2,479	3,331	3,643	310
1963	2,317	3,082	3,399	292
1962	2,199	2,866	3,170	259
1961	1,954	2,626	2,933	245

[a] Additional data are available to 1954. See earlier Annual Survey Reports.

[b] U.S. Sales of finished prescription and "otc ethical" dosage forms.

[c] Global sales are defined to include total ethical pharmaceutical sales within the United States, exports to nonaffiliated firms and sales abroad of U.S. affiliates. Figures apply to PMA member companies only. Historical series has been adjusted accordingly.

[d] Global R&D includes all ethical pharmaceutical research and development financed or conducted by U.S. pharmaceutical companies in the U.S. and abroad, and in the U.S. only by U.S. based subsidiaries of foreign-owned firms.

[e] PMA estimates based on member company budgeted figures or estimates

[f] R&D figures for 1979 and 1980 reflect a 21% increase in expenditures; however, part of this increase is due to improved reporting of expenditures in foreign countries. Adjusting for this improved reporting results in an 18% increase.

Appendix IX

R&D SCOREBOARD

COMPANY	SALES			PROFITS		R&D EXPENSES				EMPLOYMENT	
	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT ANNUAL CHANGE (1982-86)	1986 MILLIONS OF DOLLARS	PERCENT CHANGE FROM 1985	PERCENT OF SALES	PERCENT OF PRETAX PROFITS	R&D DOLLARS PER EMPLOYEE	ANNUAL CHANGE IN EMPLOYMENT (1982-86)
4 AUTOMOTIVE PARTS, EQUIPMENT											
INDUSTRY COMPOSITE	**14439.4**	**4**	**12**	**334.4**	**54**	**341.0**	**12**	**2.4**	**52.8**	**2119.2**	**6**
Champion Parts Rebuilders	110.0	9	4	0.6	-13	1.3	-1	1.2	120.9	542.0	1
Clark (J. L.) Mfg. (11)	150.6	-3	-1	17.4	8	1.3	4	0.9	4.1	793.5	-6
Clevite Industries	299.5	1	8	8.3	NA	4.6	-4	1.5	50.3	1101.0	NA
Cummins Engine	2303.7	7	11	-107.3	NA	87.5	25	3.8	NEG	3804.3	5
Dana	3695.1	-2	12	85.9	15	51.0	11	1.4	26.6	1378.4	6
Eagle-Picher Industries (11)	648.3	1	6	38.8	37	17.1	35	2.6	24.7	2164.6	3
Eaton	3811.6	4	13	137.6	11	134.1	9	3.5	60.9	3087.2	4
Echlin (8)	901.9	17	17	48.8	18	7.3	16	0.8	8.7	668.3	14
Equion (7)	58.4	26	188	2.8	NA	1.2	48	2.0	20.4	2142.9	NA
Hurco (10)	44.8	-3	13	-1.8	NA	1.6	-49	3.6	NEG	4574.6	-5
Modine Mfg. (3)	312.0	3	16	20.5	41	6.3	-2	2.0	16.2	1765.3	9
Raytech	113.5	1	-3	3.0	NA	3.3	-15	2.9	71.6	2068.8	NA
Sealed Power	665.8	7	17	28.5	5	11.4	8	1.7	22.8	1622.8	14
Smith (A. O.)	910.9	3	10	28.1	10	8.1	-2	0.9	16.4	698.3	4
Standard Products (6)	433.2	15	18	27.2	50	4.9	10	1.1	10.0	857.5	13
5 BUILDING MATERIALS											
INDUSTRY COMPOSITE	**13723.0**	**7**	**10**	**874.1**	**29**	**223.0**	**8**	**1.6**	**20.4**	**2072.7**	**5**
Ameron (11)	314.7	3	5	13.0	3	3.6	-22	1.1	21.2	1285.7	NA
Bird	184.4	-4	-8	0.4	NA	1.2	-21	0.7	143.8	1004.1	-15
De Soto	413.8	2	-7	3.9	-26	22.1	7	5.4	287.2	9995.5	4
Guardsman Chemicals	97.8	2	9	3.9	42	3.8	2	3.9	51.7	4952.3	1
Lafarge	963.8	2	2	26.0	NA	4.9	4	0.5	8.4	844.8	-1
Lilly Industrial Coatings (11)	142.6	-2	9	8.5	18	8.0	3	5.6	47.9	6795.2	7
Manville	1920.3	2	4	81.2	NA	35.8	13	1.9	25.9	1845.4	NA
Moore (Benjamin)	352.5	10	12	25.5	18	4.4	16	1.2	8.3	2424.4	NA
Owens-Corning Fiberglas	3644.4	10	11	15.6	-8	63.0	5	1.7	229.7	2626.9	4
Pratt & Lambert	193.9	5	8	8.2	15	3.8	8	2.0	25.5	2365.4	5
Preway	112.8	-13	36	-12.3	NA	1.1	-28	1.0	NEG	1056.0	17
Sherwin-Williams	1552.9	2	4	96.0	26	12.3	11	0.8	7.1	896.7	-1
Sikes (2)	87.7	10	20	4.3	39	1.0	60	1.1	12.2	891.8	13
Stanadyne	492.8	2	10	21.1	12	11.6	-2	2.4	27.7	2327.4	3
Trus Joist	179.9	36	26	8.4	11	2.6	40	1.5	16.7	1261.2	20
USG	2723.7	17	26	255.4	65	28.7	30	1.1	5.8	1322.0	14
Valspar (10)	345.2	-1	27	14.8	17	14.9	-4	4.3	55.7	7015.6	19
6 CHEMICALS											
INDUSTRY COMPOSITE	**89797.0**	**0**	**2**	**4247.5**	**8**	**3662.2**	**6**	**4.1**	**48.6**	**6092.7**	**-1**
Air Products & Chemicals (9)	1982.1	8	6	4.7	-44	61.1	20	3.1	805.0	NA	NA
American Cyanamid	3815.9	8	5	202.5	7	278.3	11	7.3	95.9	8075.6	-4
Betz Laboratories	344.4	8	8	35.5	4	13.1	9	3.8	19.6	4928.3	4
Crompton & Knowles	213.2	9	6	8.9	21	4.4	-4	2.1	27.3	3359.0	NA
Detrex	94.2	7	8	2.5	-6	2.6	60	2.8	55.5	3543.1	9
Dexter	650.1	3	5	33.6	6	27.6	7	4.2	48.8	5015.1	0
Dow Chemical	11113.0	6	2	741.0	5	605.0	11	5.4	48.9	11804.9	-2
Du Pont	27148.0	-8	-1	1538.0	11	1156.0	1	4.3	38.7	8183.0	-4
Ecolab (6)	812.9	12	6	43.7	8	10.9	53	1.3	15.0	1479.8	2
Engelhard	2289.5	1	3	53.3	-9	26.0	13	1.1	38.5	3768.1	-1
Essex Chemical	205.6	8	11	8.8	7	6.6	58	3.2	45.6	6562.4	NA
Ethyl	1579.3	2	-2	177.7	15	47.1	1	3.0	16.2	4481.4	-8
Ferro	725.2	11	5	24.1	10	11.7	8	1.6	26.0	1490.8	-2
First Mississippi (6)	268.9	-2	7	-28.1	NA	5.2	63	1.9	NEG	7809.1	NA
Fuller (H. B.) (11)	528.5	15	12	18.9	15	10.6	12	2.0	31.3	2356.9	3
GAF	753.8	3	4	80.7	60	11.4	10	1.5	9.1	2682.4	0
Grace (W. R.)	3725.7	5	1	-375.4	NA	94.2	6	2.5	NEG	2275.4	NA
Great American Management (7)	499.2	105	65	-3.7	NA	1.7	183	0.3	79.5	331.4	NA
Great Lakes Chemical	300.3	8	14	26.8	12	13.2	9	4.4	30.9	5992.3	12
Grow Group (6)	366.2	33	14	10.1	17	5.9	-11	1.6	29.5	1607.7	NA
Hercules	2615.1	1	0	226.7	15	71.1	-7	2.7	23.1	2832.1	1
HIMONT (10)	980.9	8	NA	97.3	NA	16.0	14	1.6	9.0	5713.9	NA
International Minerals & Chemical (6)	1177.7	-7	1	-79.6	NA	33.2	44	2.8	NEG	2388.5	11
Koppers	1396.4	0	5	63.2	NA	16.7	3	1.2	16.4	1530.2	-11
Lawter International	103.5	7	6	12.9	5	2.3	9	2.2	11.1	6248.6	4
LeaRonal (2)	105.0	-20	-10	6.0	-3	1.7	7	1.6	18.4	5076.9	7
Liquid Air	570.6	5	7	34.7	8	5.7	5	1.0	10.1	1292.9	3
Loctite (6)	266.8	15	5	23.2	10	10.1	15	3.8	29.5	3772.9	2
Lubrizol	985.2	8	5	78.2	10	51.2	18	5.2	39.8	10667.0	4
MacDermid (3)	86.3	-9	12	3.8	7	4.2	20	4.9	60.1	6483.1	8
Monsanto	6879.0	2	2	433.0	7	523.0	11	7.6	82.2	10115.5	1
Morton Thiokol (6)	1949.9	6	34	132.9	39	37.7	12	1.9	16.7	2106.1	27

Footnotes on page 141

Senator HARKIN. Mr. Burchett.

STATEMENT OF DENNIS BURCHETT, VICE PRESIDENT, REGULATORY AFFAIRS, UNITED AGRI PRODUCTS, AGRICULTURE CHEMICAL DIVISION OF CONAGRA, INC., ACCOMPANIED BY PAUL KORODY, VICE PRESIDENT, GOVERNMENT AFFAIRS OF CONAGRA, GRAHAM PURCELL AND BOB BOR, WASHINGTON COUNSEL

Mr. BURCHETT. My name is Dennis Burchett, and I am testifying today on behalf of ConAgra, a diversified family of companies operating across the entire food chain—from farm to table.

Our comments relate to certain business issues arising under FIFRA that we believe are not adequately addressed in the pesticide legislation under consideration by the committee.

Our recommended provisions relate primarily to patent term restoration and data compensation. The amendments recognize that the basic manufacturers are entitled to monopoly protection during the life of a patent and to extension of the patent for a reasonable period to restore time lost in entering the market because of delays attendant to the regulatory process. The basic manufacturer needs these incentives to promote research and development, but when the patent expires, manufacturers of generic pesticides should be able to compete and enter the market on reasonable terms and conditions.

PATENT TERM RESTORATION

To begin with, we support the patent term restoration provisions contained in S. 1516 which are comparable to the provisions in the bill that passed the Senate and the House last year, but only if amended to promote competition after expiration of the patent extended under the bill.

The amendment we support, first, would permit the manufacturer of a generic pesticide to conduct testing of a patented pesticide at any time during the term of the patent so long as it was for the purpose of developing information to meet regulatory requirements. Wording in S. 1516 allows testing only 2 years prior to expiration.

Second, the amendment would also permit an application for registration, together with test data, to be submitted to EPA during the term of the patent so long as the registration permitted the commercial sale of the pesticide after expiration of the patent, but not before expiration of the patent. Under the amendment, it would be a patent infringement if the purpose of the testing or the application was to gain approval to engage in such commercial activities before expiration of the patent. A just compromise for a 5-year extension. The above-mentioned provisions are included in the amendment. We would support the patent term restoration provisions in S. 1516. They are comparable to those contained in the bill that passed the Senate and the House last year.

DATA COMPENSATION

The next issue on which we wish to comment relates to the heated issue of data compensation. ConAgra recommends a new compromise on this issue which we believe strikes a proper balance between the concerns of the original data submitter and the generic producer. This issue has been a major stumbling block to passage of a FIFRA bill for the last 6 years. The problem results principally because data compensation has never been defined.

Accordingly, ConAgra has developed a new form of a compromise. The proposal we believe is in between current law and generic registration provision. The decision is also left up to the arbitrators, but in this case it simply gives some guidelines to the arbitrators, and it considers both costs of data and value of data, both of which were not put together in previous attempts.

Specifically, the amendment provides, first, that the compensation shall include a fair share of the cost of the data, leaving up to the arbitrator the exact share, based on the facts of the case. It also authorizes compensation to take into account the value of the data, but sets a maximum amount at 25 percent of the estimated net profits over the first 3 years of sales. It also provides that the total amount of compensation shall be payable over a maximum period of 3 years on such terms as to not unduly inhibit market entry of the applicant. This is in contradistinction to the *Stauffer Chemical Co.* v. *PPG* case where compensation for value was based on an amount equivalent to roughly 25 percent of the estimated net profits of PPG, multiplied by the number of pounds sold over a 10-year period.

We believe that these guidelines represent a reasonable and balanced compromise and urge your support for our recommended data compensation provisions to hopefully get FIFRA on the road and over with.

As my time is about up, I would close by urging that the ground water provisions of H.R. 2463 be adopted in place of S. 1419, and we strongly urge that the indemnification provisions of FIFRA also remain in the bill as current law.

Senator HARKIN. Mr. Burchett, thank you very much.

[The prepared statement of Mr. Burchett follows:]

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TESTIMONY
OF CONAGRA, INC.
BEFORE THE
SENATE COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
JULY 30, 1987

My name is Dennis Burchett. I am testifying today in behalf of ConAgra, a diversified family of companies operating across the entire food chain - from farm to table.

I am Vice-President for Regulatory Affairs of United Agri Products, the Agriculture Chemical Division of ConAgra which is the largest distributor of crop protection chemicals in the United States. UAP distributes a broad line of well-known pesticides manufactured by major chemical companies, and formulates and distributes its own products. UAP currently markets in 49 states and has distribution and formulation facilities in 40 states.

Accompanying me today are: Paul Korody, Vice President, Government Affairs of ConAgra and our Washington counsel, Graham Purcell and Bob Bor.

Our comments relate to certain business issues arising under the Federal Insecticide, Fungicide, and Rodenticide Act that we believe are not adequately addressed in the pesticide legislation under consideration by the Committee.

We would like to summarize the issues and submit our recommendations for your consideration and inclusion in pesticide legislation that is reported by the Committee.

Our recommended provisions relate primarily to patent term restoration and data compensation. The amendments recognize that the basic manufacturers are entitled to monopoly protection during the life of a patent and to extension of that patent for a reasonable period to restore time lost in entering the market because of the delays attendant to the regulatory process. The basic manufacturer needs these incentives to promote research and development, but when the patent expires, manufacturers of generic pesticides should be able to compete and enter the market on reasonable terms and conditions.

Open competition is the strength of our free enterprise system. Further, it would assure that farmers will have greater access to competitively priced pesticides. Based upon past experience, it is clear that vigorous competition in the pesticide industry would significantly lower the price of pesticides to farmers, which are a major part of their input costs. This would improve their overall economic situation and would be done without any cost to the U.S. Treasury.

PATENT TERM RESTORATION

To begin with, we support the patent term restoration provisions contained in S. 1516 which are comparable to the provisions in the bill that passed the Senate and the House last year, but only if amended to promote competition after expiration of the patent extended under the bill.

The amendment we support, first, would permit the manufacturer of a generic pesticide to conduct testing of a patented pesticide at any time during the term of the patent so long as it was for the purpose of developing information to meet the regulatory requirements of FIFRA or the pesticide tolerance requirements of FDA.

Secondly, the amendment would also permit an application for registration, together with test data, to be submitted to EPA during the term of the patent so long as the registration permitted the commercial manufacture and use of the pesticide after expiration of the patent but not before expiration of the patent. Under the amendment it would be a patent infringement if the purpose of testing or the application was to gain approval to engage in such commercial activities before expiration of the patent.

Under current law, as a result of a 1984 decision of the U.S. Court of Appeals for the Federal Circuit in the case of Roche Products v. Bolar Pharmaceutical Co. it is considered a patent infringement for a generic manufacturer to use a patented product during the term of the patent to develop test data necessary to register the product after expiration of the patent. The court decision delays any testing until after the patent expired, thereby extending the patent owner's monopoly beyond the patent expiration date, since it requires as long as from five to seven years for the manufacturer of a generic pesticide to reproduce the test data needed to obtain a registration from EPA.

S. 1516 and the bill that passed the Senate and House last year would restrict to a period of two years before a patent expires the time during which the manufacturer of a generic pesticide may conduct testing of a patented pesticide to develop the data necessary to obtain a registration from EPA after the patent expires. In our view, the two year limitation is unnecessary and discriminatory inasmuch as it takes substantially more time to develop the test results needed to satisfy EPA's registration requirements.

Similarly, S. 1516 would prohibit a generic manufacturer from submitting an application for registration to EPA prior to the expiration of the patent, even though the purpose is to obtain the necessary regulatory approval for the commercial manufacture and distribution of the pesticide after the patent expires. It often takes EPA several years to assess test data submitted to it and act on applications for registration -- even when the applicant is a generic manufacturer. As you know, EPA is shorthanded with many demands on its resources, and at the present time review of registration applications for generic pesticides is at the end of its list of priorities.

The combination of these two provisions in S. 1516 seriously delays the ability of a generic manufacturer to enter the market after a patent expires.

We urge your support for an amendment that would cure these defects.

If the above mentioned provisions are included in the amendment, we would support the patent term restoration provisions in S. 1516. They are comparable to those contained in the bill that passed the Senate and the House last year. We note that S. 1516 contains the following salient provisions with which we are in agreement:

a. Up to a 5 year patent extension to compensate for regulatory delays, 2 years if the regulatory review period began before enactment of the bill, none if the regulatory review process were completed by enactment of the bill.

b. All formulations of a pesticide containing the identical active ingredient would be considered the same pesticide.

c. No pesticide would be the subject of more than one patent extension.

d. In no event may more than one patent be extended for the same regulatory review period for any product.

The patent term extension provisions of S. 1516 provide significant relief to current holders of patents. They would extend the term of a patent to compensate the patent holder for marketing time lost in the regulatory review process. However, once the patent expires there should be free and open competition in the market place. Failure to adopt our proposed amendment would result in effectively keeping competition out of the market and maintaining monopoly protection that would continue well beyond the extended patent provided by the bill.

DATA COMPENSATION

The next issue on which we wish to comment relates to data compensation. ConAgra recommends a new compromise on this issue which we believe strikes a proper balance between the concerns of the original data submitter and the generic producer.

Under current law if a generic manufacturer wishes to enter the market after a patent for a pesticide has expired he has the choice of replicating the health and safety tests that were performed by the basic manufacturer or agreeing to pay the basic manufacturer compensation for use of the data previously submitted to EPA. If he elects to pay compensation, the law does not set any standard for determining compensation but leaves it to be decided by agreement by the parties concerned, or failing that through arbitration. S. 1516 makes no change in these provisions of current law.

In the one award that has been made as a result of arbitration (Stauffer Chemical Co. v. PPG, July 7, 1983), the arbitrator required payment of approximately five times "the direct aggregate testing cost of required pre-registration data" or about $15 million for data that cost the basic manufacturer $2,930,000 (in 1983 dollars). Arbitration is a costly process - it is time-consuming and expensive. Unless a standard is included in the law, this award stands as a precedent for future cases and a deterrent for the entry of generic pesticides onto the market.

Generic pesticide producers are looking at a range of options. Most favor the Kassebaum bill which would repeal outright the whole data compensation process, thus putting pesticides on the same footing as Congress approved in 1984 for human pharmaceuticals. There is great logic and appeal to this approach since EPA has already reviewed the data and satisfied itself as to the safety of the data. Further, the basic manufacturer has already been rewarded for his having conducted research and development of the pesticide by the patent protection provided for the original discovery. Patent term extension provisions would expand on this protection for future registrations. On the other hand, it is recognized that there may be strenuous opposition to this kind of proposal.

Accordingly, ConAgra has developed a new form of compromise that would set a general standard for the arbitrator. It would cap the total cost at a reasonable level, giving the basic manufacturer compensation towards his cost of developing the data and also recognition of the value of the data to the generic manufacturer by enabling him to enter the market without the delay attendant to replicating the original tests.

Specifically, the amendment provides, first, that the compensation shall include a fair share of the cost of the data, leaving up to the arbitrator the exact share, based on the facts of the case. It also authorizes compensation to take into account the value of the data, but sets a maximum amount at 25 percent of the estimated net profits over the _first three years_ of sales. It also provides that the total amount of compensation shall be payable over a maximum period of three years on such terms as not to unduly inhibit market entry of the applicant. This is in contradistinction to the _Stauffer Chemical Co. v. PPG_ case where compensation for value was based on an amount equivalent to roughly 25 percent of the estimated net profits of PPG, multiplied by the number of pounds sold over a _ten year period_.

We believe that these guidelines represent a reasonable and balanced compromise and urge your support for our recommended data compensation provision.

MISCELLANEOUS PROVISIONS

While the business issues of greatest concern to ConAgra are the matters discussed above, ConAgra has an interest in two other issues; namely defensive data and early arbitration.

From time to time, the Administrator may request existing registrants to provide additional data to maintain in effect an existing registration. This type of data is often referred to as "defensive data." We support the type of provision included in section 206 of S. 1516, under which an existing registrant who offers to share with another registrant the cost of developing the data may examine the data and rely on the data to maintain its registration in effect. In other words, an existing registrant could not be shut out and forced to needlessly spend resources in developing duplicative test data. If registrants are unable to agree on cost sharing arrangements, the matter may be submitted to binding arbitration.

Finally, with two exceptions, we support the provision in S. 1516 that would permit a person who intends to file an application for registration of a generic pesticide to obtain a decision, before he files an application, of the compensation he must pay to the original data submitter for use of that person's data. In such event, he would not be bound to pay the amount of the award should he decide not to file an application for registration. It would enable generic manufacturers to make a rational decision whether or not to enter the market.

First, we recommend that the early arbitration provision should not be limited to pesticides for which the term of the patent has expired. As we had stated previously in our testimony, arbitration is a costly and time-consuming process. If the generic manufacturer wishes to enter the market immediately after the patent expires, he should be able to obtain information as to the cost of buying into use of the basic manufacturer's data early - even before expiration of the term of the patent.

In addition, we urge deletion of language included in section 204 of S. 1516 that would require any person who seeks to cite the same data under subsequent arbitration to pay the fees of the arbitrator and attorney fees of the original data submitter. We believe this provision is inappropriate since issues in subsequent arbitrations may differ from the first arbitration because of differences in size, location, and other factors relating to the person seeking early arbitration. Further, the lapse of time between the two arbitrations may raise significant differences in any valuation that an arbitrator may place on the data.

We would be pleased to respond to any questions you may have on our proposals.

Senator **Harkin**. Mr. Engel.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURING ASSOCIATION [CSMA], WASHINGTON, DC

Mr. **Engel**. Good afternoon, Mr. Chairman. My name is Ralph Engel, and I am president of the Chemical Specialties Manufacturers Association [CSMA].

CSMA has a membership of more than 400 member companies and represents the nonagricultural pesticide industry including disinfectants and sanitizers and a wide variety of other pesticides for home, industrial and institutional use.

There are several aspects of S. 1516 that we can support, but there are also problems that need to be addressed. Because of time constraints, we would like to focus first on the issue of reregistration fees. The EPA reregistration process benefits the general public, not just those who produce products to be registered. These reregistration costs should be paid with public funds, not with special fees. Pesticides should not be singled out for special user fees when other preclearance statutes are specifically exempt from user fees or registration fees. Congress has consistently taken steps to prohibit user fees for the registration of drugs, thus setting a clear precedent.

S. 1516 calls for a new section requiring that the Administrator shall charge and collect from the registrants of pesticides, listed for reregistration, a total fee of between $50,000 and $750,000, payable in annual increments over 5 years depending on whether active ingredient's gross sales exceed $10 million, and whether the pesticide was first registered before October 1, 1978. There is absolutely no distinction as to whether the pesticide is used for food or feed, nor is any reduction provided for minor uses, antimicrobials, or small business registrants. As a result, the registrant of a specific disinfectant with annual sales of $10,000 will pay the same $100,000 fee as the registrants of a pesticide for use on food crops with sales of approximately $10 million.

We oppose the adoption of reregistration fees for the very inequities described above in the fee schedule proposed in S. 1516.

Many CSMA manufacturers produce disinfectants and sanitizers (antimicrobial products) registered under FIFRA. These products contain active ingredients for home, institutional and dairy farm use in the cleaning and sanitizing of laundry, medical equipment, lavatory facilities, and milking equipment. Manufacturers of some of these products with annual gross sales under $20,000 will be paying more in reregistration fees than they obtain from gross receipts.

Reregistration fees will, in fact, control which antimicrobial and pesticide products will be available in the marketplace.

In addition to our concerns about S. 1516, we at CSMA believe that another key issue needs to be addressed in pursuing FIFRA amendments.

Under California law, passed in 1984, that State is establishing a program for filling pesticide data gaps. In implementing this State law, California is adopting a definition of what constitutes a data gap, establishing a list of studies that need to be done, and creating a timetable for filling these voids. Unfortunately, the State has no motivation to take notice of or incorporate into its program the efforts of the Congress and EPA to establish reregistration timetables and data call-ins to fill many of these same gaps.

In essence, in attempting to establish its own expedited reregistration program to fill data gaps, the State is actually establishing an agenda and timetable which is in conflict with the Federal requirements. CSMA recognizes the need to fill data gaps at both the State and Federal levels, and is not suggesting that State discretion be preempted by EPA decisionmaking. However, CSMA urges that test procedures among the States and EPA be coordinated and synchronized so that only one set of tests need to be generated within the same timeframe using the same protocol.

Unnecessary, repetitive and redundant testing not only consumes valuable time and resources, but also delays the closing of data gaps. Valuable time and resources, which could be used to develop new data, are wasted in refocusing on gaps that have already been, or are in, the process of being filled.

Other States, such as New Jersey and Massachusetts, have indicated interest in establishing their own data gathering processes as well.

CSMA is suggesting language which would not only keep EPA and the States on equal footing, but would also allow EPA to take advantage of the testing resources of the States, for example, laboratories, toxicologists, and vice versa.

Mr. Chairman, the language in our testimony reflects some changes from before, and takes into consideration suggestions of committee staff and others. We believe we will be able to provide language shortly that all will support. It is important to recognize that this language is not intended to preempt a State from asking for additional data. The language is only to coordinate the testing procedures and protocols as between States and the Federal Government. Thank you very much.

Senator HARKIN. Thank you very much.

[The prepared statement of Mr. Engel follows:]

TESTIMONY OF RALPH ENGEL
PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
UNITED STATES SENATE
JULY 30, 1987

My name is Ralph Engel; I am president of the Chemical Specialties Manufacturers Association (CSMA) located at 1001 Connecticut Avenue, N.W., Washington, D.C.

CSMA has a membership of more than 400 firms engaged in the manufacture, formulation, distribution, and sale of pesticides, antimicrobial products, automotive chemicals, detergents and cleaning compounds, and polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Specifically, CSMA represents the non-agricultural pesticide industry, including disinfectants and sanitizers; home lawn and garden pesticides; and a wide variety of other pesticides for home, industrial and institutional use.

I would like to take this opportunity to commend you, Mr. Chairman, along with the committee for your continued interest and concern about FIFRA legislation.

CSMA CONCERNS WITH S-1516

Although there are several aspects of S-1516 that we support, there are also problems which we addressed last year. We would like to focus briefly on the following issues: A) reregistration timetables; B) reregistration fees; C) inert ingredients; D) interim administrative review and cancellation procedures; E) Data Disclosure to States; F) Indemnification; G) Commercial Applicator Certification; and H) Expert Opinion

A. REREGISTRATION TIMETABLES

The bill establishes an EPA mandated deadline for submission of data resulting in automatic cancellation if the deadline is not met, without allowing the administrator the flexibility to address potential problems in all cases. This approach is too severe since the registration of an active ingredient would be cancelled without hearing if any data, no matter how insignificant, is not received within the specified time period. As proposed, any unfilled "Outstanding Data Requirements" identified by the registrant, regardless of importance, would trigger a cancellation. A pesticide registrant should be given an opportunity to review the Agency's determination of the existence or importance of missing data prior to cancellation.

In addition, S-1516 requires that the Administrator "complete reregistration of each pesticide within one year of receipt" of the data, a very unrealistic goal. These reregistration data submissions will not be evenly spaced. In fact, most data will be completed will not be evenly spaced. In fact, most data will be completed in the last third of the nine-year cycle, forcing the EPA to attempt to reregister a disproportionate number of products in a relatively short time. It is unlikely that EPA could comply with these deadlines and still perform its other mandates. The Administrator should be given sufficient time to adequately address the reregistration process, with built-in flexibility to deal with unexpected problems in the system. Pursuant to the investigative and oversight congressional functions, the House and Senate can periodically examine the process to determine if any abuses are taking place.

We propose the following changes:

First, the Administrator should be given more flexibility by defining the "extraordinary circumstances" by which he can extend the time limit for submission of data, including non-negligent loss of laboratory results, destruction of the laboratory, unavailability of laboratory facilities, major animal loss or similar unanticipated problems.

And second, since the Administrator cannot reregister a product in one year from the date he has obtained all the required data, he should be given an extra year and, if necessary, a further two-year extension for "extraordinary circumstances."

We believe the EPA can complete the reregistration process in eight to twelve years. The Agency might be able to spread out its manpower and other resources to meet all of its objectives if the timetables contained more flexibility. S-1516 builds into the process two major manpower peaks - reviewing the studies and processing the data. If these peak loads are more reasonably distributed and more realistic review periods are implemented, the Agency will have an opportunity to manage its existing resources to accomplish the reregistration program without the need for such fees.

B. REREGISTRATION FEES

Any system of reregistration fees would, in effect, result in taxing a few to finance a regulatory system that benefits the vast majority. When government services benefit society generally, the expense of those services must be borne by the taxpayers at large, not by individuals. The primary purpose for requiring the reregistration of pesticides is to protect public health and safety. Thus, the EPA reregistration process benefits the general public, not just those who produce products to be registered. These reregistration costs should be paid with public fund[illegible] not with special fees.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and rodenticide Act (FIFRA), there are, requirements for the preclearance of a specific commercial product - drugs and pesticides - prior to its manufacture, sale and distribution. In each case the Federal Government acts as a clearing house, collecting and evaluating data, and ultimately making the decision of whether or not to grant reregistrations for pesticides or new drug applications. In each case the registration and preclearance of products broadly benefits the general public.

Pesticides should not be singled out for special user fees when other preclearance statutes are specifically exempted from user fees or registration fees. The Congress has consistently taken steps to prohibit user fees for the registration of drugs, thus setting a clear precedent.

In passing the Federal Food and Drug Administration's budget for FY '85, the Congress specifically replaced $5 million that FDA had indicated would be made up through the imposition of user fees. In replacing these funds, the report of the House Appropriations Committee stated that FDA had received no funds "for further consideration or development of a user fee proposal." Congress' reinstatement of the $5 million in FDA's appropriations, coupled with the committee report, was tantamount to a specific legislative directive that Agency funds not be spent to develop a user fee proposal.

On December 13, 1985, the House and Senate conference committee voted to prohibit the Food and Drug Administration from imposing user fees for review of new drug applications for FY '86. The conferees accepted the House prohibition against user fees, contained in H.R. 3037, the Agricultural, Rural Development, and Related Agencies Appropriations Bill.

S-1516 calls for a new section 3A(j) requiring that "the Administrator shall charge and collect from the registrants of pesticides listed for reregistration pursuant to subsection (d)(2) a total fee of between $50,000 and $750,000 payable in annual increments over five years depending on whether the active ingredient's gross sales exceeds $10,000,000 and whether the pesticide was first registered before October 1, 1978. There is no distinction as to whether the pesticide is used for food or feed nor is any reduction provided for minor uses, anti-microbials or small business registrants. As a result, the registrant of a disinfectant with annual sales of $10,000 will pay the same $100,000 fee as the registrants of a pesticide for use on food crops with annual sales of $9,999,999.

In addition to opposing fees in principle, we oppose the adoption of reregistration fees for the very inequities and abuses described above in the fee schedule proposed under S-1516.

First, a system of pesticide reregistration fees would dramatically increase product development costs, reduce innovation and have an unfair and disproportionate impact on small businesses. Second, by establishing only a flat fee, there is insufficient differentiation between agricultural and non-agricultural products. Third, the fee is not based on the actual time it takes EPA staff to register the product. Fourth, the ultimate costs of a reregistration fee program may, in part, be borne by pesticide users and consumers in general.

Many CSMA manufacturers produce disinfectants and sanitizers (antimicrobial products) registered under FIFRA. These products contain active ingredients for home, institutional and dairy farm use in the cleaning and sanitizing of laundry, medical equipment, lavatory facilities, milking equipment, etc. Manufacturers of some of these products with annual gross sales under $20,000 will be paying more in reregistration fees than they obtain from gross receipts.

Reregistration fees will, in fact, control which antimicrobial and pesticide products will be available in the marketplace. Registrants of some products may choose to accept voluntary cancellation rather than paying reregistration fees. Certainly the proposed fees will not curtail the reregistration of very high-volume pesticides that are profitable but access to some older products, with limited volume and specialized uses, for which the market is relatively small, may disappear because of the fees. If the fees make it unprofitable for the registrants of these products to reregister them, a vast number of pesticide and antimicrobial products will be unavailable to manufacturers, users, and consumers. In our judgment, fees should not determine the availability of products, especially those necessary to insure our high standards of public health.

Not only will existing products be affected by reregistration fees, but future products, on the cutting edge of technology, might be curtailed unless marketed on a high volume, high profit basis. Innovation for pesticide and antimicrobial products could be severely affected.

Lastly, if such a reregistration fee were coupled with a newly proposed registration fee, and sharp increases in existing registration fees at the state level, the costs of registering products will significantly increase. All those groups, organizations and individuals who manufacture, sell, distribute or use pesticide products will be directly or indirectly affected. Consequently, we respectfully request that the user fee program be deleted from any bill reported.

Although we do not address registration fees here because such fees are not included in S-1516, we should state that CSMA is unequivocally opposed to registration fees for the same reasons mentioned above.

C. INERT INGREDIENTS

Although we agree that the Agency should address those troublesome inert ingredients causing an end-use pesticide to be a hazard to man or to the environment, we differ with the approach taken in S-1516. We would like to identify some basic concerns with this proposal:

1. Inert Criteria

We disagree that widespread exposure or use should alone be a trigger to the listing of inert ingredients, thus requiring additional testing. An inert ingredient should be listed only if a risk assessment indicates that a significant hazard may exist from the use of the inert ingredient contained in the pesticide product.

S-1516 provides that the Administrator shall publish a priority list of inert ingredients that fall into three categories. 1) "inert ingredients which appear to cause a pesticide to meet or to exceed a criteria for initiating an interim administrative review" would be placed on the list.
2) "inert ingredients for which additional data are reasonably necessary to evaluate whether the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment," "that are similar in molecular

structure to a chemical that is oncogenic mutagenic, or teratogenic or causes another similarly significant adverse effect," and, "has significant use in pesticides." would be listed as well.

3) inert ingredients where "there is significant exposure from pesticides."

Under the third category, widespread exposure or use alone should not be a trigger to listing an inert ingredient under subsection (g). A pesticide containing an inert ingredient should be listed under this subsection only if a risk assessment indicated that a significant hazard may exist from the pesticide use.

2. The Dynamic List of 50 - 75 Inerts

S-1516 contains an initial list of 50 inerts, with 25 more which may be added. This list is supposedly dynamic, with inerts coming on and off the list. The ultimate purpose is to establish a system by which the Agency could review and require testing on more than a thousand inerts over the next decade.

By establishing a minimum floor of 50 inerts, the Agency will be forced to review inerts that the Administrator might not have chosen to examine, because they do not pose a risk to man or the environment. The development of an unlimited inert list is resource intensive and will divert considerable agency resources away from other tasks, including registration and reregistration programs.

By establishing a ceiling of 75 inerts, but no minimum amount, the Agency could examine any troublesome inert without being forced to consider more than 1,000 inerts. It would allow the Administrator to retain his flexibility, to establish priorities, and to deal effectively with ANY INERT that presents a hazard to man or to the environment. We would recommend substitute language that would read as follows: "the priority list shall consist of not more than seventy-five (75) inert ingredients."

Additionally, a delisting procedure should be specified by S-1516 which would effectively remove from the list those inert ingredients found not to present a hazard to man or the environment. Without such a procedure an inert could remain listed indefinitely to its economic detriment without environmental or health justification.

E. INTERIM ADMINISTRATIVE REVIEW AND CANCELLATION PROCEDURES

Nearly everyone agrees that the cancellation procedures take too long and should be streamlined. S-1516, however, interjects new controversies into this process at several levels.

Although the proposal retains the language of the Grassley/Allan Amendment, (FIFRA Section 3(C)(8)), which requires a validated test or other significant evidence prior to initiating an interim administrative review, Sec. 301 (a)(8)(B)(ii) and (iii) undercut its meaning, establishing a risk-only trigger for starting an interim administrative review. Since nearly all products have some level of risk, the new sections would defeat the objective of Grassley/Allan to avoid "hit lists" being established without appropriate scientific evidence.

We suggest that the risk trigger be replaced by the Special Review criteria developed by the EPA and published in the Federal Register on November 27, 1985. Since this criteria has had ample opportunity for public comment and review prior to becoming a final rule, we recommend this language as a replacement for the trigger in S-1516.

It is important to note that the Administrator still has the emergency authority to act in a crisis to eliminate the notice requirements of FIFRA Section 6(b) and go directly to suspension. The provision of existing Section 6(b) provides "in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health", then he may waive the notice requirements. Thus, the Administrator already has appropriate existing authority to act in a crisis or emergency.

Two important concerns we have with the amendments to Section 6 are: 1) a shift to informal rulemaking; and 2) establishing a "right-of-standing" for all regardless of economic interest.

S-1516 would allow the Administrator to change the labeling of a pesticide by informal rulemaking. Since labeling of pesticides place regulatory responsibilities upon registrants and is the basis for civil and criminal liability, all labeling requirements should be subject to the safeguards of formal rulemaking.

The right of a pesticide registrant or user to examine EPA's proposed restrictions in a cancellation hearing is one of the major strengths of FIFRA. This procedure allows those who have invested time and money in registering a pesticide, and those who depend on the pesticide to protect their property, to examine the scientific basis for EPA's proposed restrictions. This process is the best method in any environmental law for assuring a proper, scientifically sound, decision. S-1516 would allow EPA to bypass the cancellation hearing, a hearing that must be available to registrants and users as a final resort.

The proposal to add a new "informal rulemaking" as an alternative to a cancellation hearing allows EPA to impose pesticide restrictions without allowing interested parties to go to a cancellation hearing. In short, EPA could, through an "informal rulemaking", impose restrictions on a pesticide and neither the registrants nor the users would have an opportunity to dispute them in a cancellation hearing. If the Agency has some concern about a pesticide, it should initiate a Special Review or a cancellation hearing, but it should not deny the registrant or user recourse to the cancellation hearing.

To establish a "right-of-standing", the proposed amendments to Section 6 provides for a hearing on any cancellation requested by a person adversely affected by the notice, "including a person without an economic interest in the pesticide." As currently written and interpreted, only those parties with an economic interest in FIFRA (i.e., pesticide registrants and users) have the right to demand a cancellation hearing. This limitation on the ability to demand a hearing is appropriate because Congress specifically empowered EPA, not other groups, to protect the public and the environment. Additionally, there is a real concern that frivolous or harassing challenges would be brought. We oppose amending FIFRA to allow those without an economic interest in a pesticide to demand a cancellation hearing, there is already ample opportunity for public input and participation in the regulation of pesticides.

Although nearly everyone agrees in principle that the State or State agencies should have access to registration data, S-1516 creates a new subsection 10(h) that provides for the disclosure of "any data or information acquired under the authority of this Act if the laws of the state assure that the owner of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the state than is provided by Sections 10 and 3 of this act". Since many states have laws inconsistent with each other as well as Federal FIFRA, it is unlikely that states could take advantage of this section without changing many of their own laws, a difficult and time-consuming process.

We suggest that the State or State agency enter into a written cooperative agreement with

EPA so as to certify that anyone denied access to the information at the federal level would also be denied access at the state level. Thus, it would be possible to get the appropriate data to the state or state agency without jeopardizing the confidentiality of the data or forcing each state to change its laws to conform to federal FIFRA.

F) **INDEMNIFICATION**

Whenever as a result of an imminent hazard the EPA suspends and/or later cancels the registration of a pesticide, the Agency is required by Section 15 FIFRA to indemnify owners of existing stocks that can no longer be sold or used and to pay for the disposal of those stocks. We support the present statute's handling of the problem.

S-1516 would require the Administrator to make a request of the Committees on Appropriations of the House and Senate for a specific appropriation of funds which must be granted in advance of any payment. The right of indemnification would appear to be effectively eliminated.

Such a proposal, would have a disproportionate impact on small manufacturers, marketers, processors, and distributors, as well as the basic manufacturers or suppliers. Severe dislocation would occur at each level.

In weighing the risks and benefits and economic impact of regulatory decisions, the Agency ought to take into consideration the economic dislocation that might occur as a result of its decision. In addition, the EPA should consider alternatives to ban a product or to immediately remove the existing stocks from the marketplace.

Also, there is an important seasonal impact on the marketplace. For many home, lawn and garden products, marketers and distributors may stockpile supplies and ingredients over the summer and winter for heavy spring usage. Consequently, the timing of an agency action is critically important to everyone.

Because we share the Agency's concern about the impact that indemnification might have on its operating budget, we would recommed that provisions be made to obtain the funds from general revenues with descretion given to the Committees on Appropriations only to determine the appropriateness of the amount not to deny the indemnity right itself to owners of suspended or canceled stocks.

G) **COMMERCIAL APPLICATOR CERTIFICATION**

Section 401 of the Act would require all commercial applicators of any pesticide to be registered and certified. Thus, maids and janitors who use disinfectants and bug sprays in the course of their responsibilities would require such registration and certification. It would make no sense to restrict these employees of the home owner when the home owner himself is not so restricted. The solution to this dilemma is to exempt commercial applicators of antimicrobials and consumer products from the certification and registration requirement.

H) EXPERT OPINION

Section 506 of S-1516 proposes amending Section 6 of FIFRA by defining "expert opinion" as "additional information" regarding unreasonable adverse effects on the enviroment which must be submitted to the Administrator.

Inclusion of this amendment in the bill would circumvent the recent United States District Court for the District of Columbia decsion filed February 8, 1980 (*Chemical Specialties Manufacturers Association v. Enviornmental Protection Agency*, Civil Action 77-1938). This suit was brought by two Associations to contest EPA's interpretation of the meaning of Section 6(a) (2) which requires submission of "additional factual information regarding unreasonable adverse effects on the enviroment of the pesticides" to be submitted to the Agency. In his opinion with respect to the obligation to report expert opinion, Judge Aubrey E. Robinson, Jr. stated:

> While the EPA's memorandum suggests that expert opinion is included in Section 6 (a) (2), it is mistaken. If Congress had intended to give Section 6 (a) (2) such broad scope, it would not have limited the information required to facts.

Inclusion of the Amendment would modify existing judicial precident and expand the reporting requests beyond those originally intended by the Congress.

Accordingly, CSMA opposes this provision and requests that the Amendment be deleted.

II. CSMA CONCERNS ABOUT ADDITIONAL FIFRA ISSUES

In addition to our concerns about S-1516, we at CSMA believe that several other issues ought to be addressed while we pursue FIFRA amendments in 1987.

A. Coordination of Pesticide TEST Requirements Among the States and EPA

Under California law, passed in 1984, that state is establishing a program for filling pesticide data gaps. In implementing this state law, California is adopting a definition of what constitutes a data gap, establishing a list of studies that need to be done, and creating a timetable for filling these voids. Unfortunately, the state has no motivation to take notice of or incorporate into its program the efforts of the Congress and EPA to establish reregistration timetables and data call-ins to fill many of these same gaps.

In essence, in attempting to establish its own expedited reregistration program to fill data gaps, the state is actually establishing an agenda and timetable which is in conflict with the federal requirements. CSMA recognizes the need to fill data gaps at both the state and federal levels and is not suggesting that state discretion be preempted by EPA decision-making. However, CSMA urges that test procedures among the states and EPA be coordinated and synchronized so that only one set of tests need to be generated within the same time frame.

Unnecessary repetitive and redundant testing not only consumes valuable time and resources but also delays the closing of data gaps. Valuable time and resources which could be used to develop new data are wasted in refocusing on gaps that have already been or are in the process of being filled.

Many low-volume, low profit specialty products, including antimicrobial products, may be discontinued because neither the registrant, the formulator, nor the state will pay for the additional tests required on active ingredients. Many non-agricultural, minor use products could also disappear. Unrealistic timetables for implementing and generating these needed studies could cause some of these products to be dropped from the market.

Other states, such as New Jersey and Massachusetts, have indicated interest in establishing their own data requirements as well. Other states could follow these examples and begin requesting additional data in conflict with that required by EPA. These additional data do have a serious impact.

CSMA is suggesting legislative language which would not only keep EPA and the states on equal footing but would also allow EPA to take advantage of the testing resources of the states (e.g., laboratories, toxicologists) and vice-versa. It would also assure that effective, low cost products would continue to be made available to the farmer and consumer. CSMA suggests amending Section 3(c)(2)(B) of FIFRA by adding the following new subsection at the end:

(IV) Whenever tests of a type specified in the guidelines promulgated under 3(C)(2)(A) or (3)(2)(B) are requested by more than one state or federal agency, such tests with respect to such aspects as test protocols, timetables, and standards of review, shall be coordinated and synchronized among the agencies so as to avoid unnecessary repetion and redundancy. Within one year after enactment of this law, the Administrator shall, by rule, develop and implement procedures, for such coordination and synchronization by the Administrator so as to result in identical and concurrenttests acceptable to all the Agencies. In the case of unresolvalbe dispute, he shall submit the facts to the FIFRA Scienitific Advisory Panel and shall make a final determination implementing the Panel's recommendation.

B. State Political Subdivision Under Section 24(a)

During the 1980's many political subdivisions of a state, such as a city, county or township, have attempted to exercise the same pesticide jurisdiction as a state. Such attempts to usurp the authority of the state are contrary to the legislative history of FIFRA. In passing the 1972 FIFRA amendments, Congress granted limited pesticide regulatory authority to states. The legislative history shows that Congress intended, in some cases, to share its authority with the states, but not with local jurisdictions.

It is evident that statutory language is necessary to inform local jurisdictions of Congress' intent to prohibit pesticide regulation below the state level. In adding Section 24(a) to FIFRA in 1972 (Public Law 92-516), Congress made clear that it was extending limited regulatory authority to the states, but not to local jurisdictions. On June 7, 1972, the Senate Agriculture Committee reported out the previously passed House bill. The committee report (Senate Report No. 92-838, 92nd Cong., 2nd Sess.) accompanying the bill states:

The Senate Agriculture Committee considered the decision of the House Committee to deprive political subdivisions of States and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty States and the Federal Government provide sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any, local authorities whether towns, counties, villages, or municipalities have the financial wherewithal to provide necessary expert regulation comparable with that provided by the State and Federal Governments. on this basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the States, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, p. 4008 (1972).

The Senate Commerce Committee offered an amendment to that bill specifically to allow local jurisdictions to regulate pesticides, and the Senate rejected it by a vote of 71-0.

Despite this extensive legislative history, there have been attempts by various political subdivisions of fifteen or more states to regulate the sale or use of pesticides or to request generation of new data. Local jurisdictions are enacting restrictions that create considerable hardships for farmers, foresters, and homeowners, as well as for manufacturers.

Local regulations not only place burdens on pesticide users, but are unnecessary in light of the extensive system of state and federal regulation. Local jurisdictions are also not equipped to make the scientific decisions needed to regulate pesticide use properly.

To solve the problem of local pesticide regulation in the 1980's, we recommend an amendment to Section 24(a) of FIFRA, to limit pesticide regulatory authority to the states. With the amendment, the section would read: "A State, but no political subdivision of a State, may regulate the sale and use of any federally registered pesticide . . ."

We support this amendment and believe that the statute ought to reflect the Congressional intent that political subdivisions below the state level should not regulate the sale or use of pesticides.

C. Distinction Between Agricultural and Nonagricultural Pesticides:

In 1978, Congress added a new requirement to FIFRA (Section 25(a)(1)) directing that regulations prescribed by the Administrator to carry out the Act shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk, and the appropriate data for evaluating such risk, between agricultural and nonagricultural pesticides. This amendment extended an existing provision that required the Administrator to take into account the differences in concept and usage between various classes of pesticides, mandating that such a distinction be applied in prescribing and evaluating data for non-agricultural pesticides.

We have now found that state legislators and some state regulatory agencies similarly are not taking into account the differences between agricultural and non-agricultural pesticides in proposing legislation and regulations. In recent comments to one state, CSMA found it necessary to point out that the proposed regulations particularly failed to consider disinfectants and sanitizers. Therefore, we requested significant modifications to or withdrawal of the regulations until they could be rewritten to take into account the appropriate differences.

Concerning FIFRA amendments, we specifically recommend that a new Section 24(d) be added, mandating that states take into consideration the differences between agricultural and non-agricultural pesticides. In promulgating any regulations, policies, or protocols pertaining to the sale or use of pesticides within a state including the imposition of taxes and registration fees, the state should take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides. In making a request for data submitted in support of a Federal registration, the state should also take into account the difference in concept and usage between agricultural and non-agricultural pesticides.

With this provision included in any FIFRA amendment, we believe some pressures for inappropriate state regulation would disappear because state regulators would have a federal mandate to consider the various types of pesticides when they propose appropriate regulations.

An alternative to a FIFRA mandate would be a change in the definition of a "pesticide" which would differentiate between agricultural and non-agricultural uses. States frequently incorporate the FIFRA definition of pesticide in their legislation but do not include the Section 25(a)(1) distinction.

D. To Use Any Registered Pesticide in a Manner

Inconsistent
With Its Labeling

A new Section 2(ee)(5) should be added to permit use of one pesticide in the formulation of another registered end-use product or to allow a registered product to be repacked into another end-use product unless prohibited specifically by the labeling. This provision was included in H.R. 5203 (97th Congress), and had widespread support in the House.

Another new Section 2(ee)(6) should be added to specify that a misuse statement is not required on the label of all pesticides as is required by regulation. Currently, household disinfectants and sanitizers are required to use the statement "It is a violation of federal law to use this product in a manner inconsistent with its labeling." Such statements are not believable, and the users will simply refuse to believe they may be prosecuted if they do something other than that listed on the label. Under Section 2(ee), there should be an exemption for those "applying a household cleaning product containing a disinfectant or sanitizer active ingredient, in household or institutional cleaning uses."

E. Section 10. Protection of Trade Secrets and Other Information

We would like to recommend two changes in Section 10 of FIFRA.

1) Freedom of Information Act (FOIA) Procedures

Under FOIA procedures, the EPA routinely releases the product label and internal EPA memos on the review of submitted data as soon as the product's registration is granted. The time lag between registration and sales can be quite lengthy, but the EPA does not recognize that giving this information to a competitor before sales begin amounts to disclosure of highly confidential marketing information, e.g., that a company intends to enter a specific market with a specific product.

Disclosure of any information on the intent to market a pesticide should commence at the time a product is initially introduced into commerce for sale, rather than at registration, unless the disclosure is specifically necessary to protect against a suspected unreasonable risk to health or the environment. Since all interested members of the public will have an opportunity to review this data prior to registration (under H.R. 2463), only business competitors will be denied access to the data.

2) Notification About Information Requested

Although the Administrator should notify the submitter of his intent to disclose trade secrets under Section 10(d)(3), disclosure of other data and information is not covered under FIFRA. A submitter should have the right to be advised that any of its data have been requested and that the agency plans to release it.

F. Section 3. Registration of a Pesticide

1) Section 3(c)(3).

Another major problem of great concern to our industry has developed and we believe it can only be solved with specific direction from Congress. Nonagricultural pesticide manufacturers seeking to obtain "me-too" registrations or just simple amendments to existing registrations are experiencing unreasonable delays in the processing within the Registration Division of EPA's Office of Pesticide Programs. It is not unusual for these applications or amendments to sit in the Division in excess of a year or more. In many cases the processing of these items could take only a few minutes if registration personnel would just take time to process them. But the result has been and continues to be the creation of an unnecessary and huge backlog of applications for me-too products and amendments. Obviously, absent such processing a firm is precluded from marketing its products.

We have brought this problem to the attention of the Agency and have had meetings with EPA personnel aimed at streamlining the registration process with respect to these long delays. The Agency has been very candid with us and has stated that as a result of pressure from Congress, and particularly this committee, it has utilized just about all registration personnel in other areas such as the development of reregistration standards. Additionally, the Registration Division is giving priority to applications for new chemicals and new uses of existing chemicals while relegating the me-too registrations--that is registrations of products similar to those already on the market--to a low priority. Thus very few of these applications or amendments are being processed. Most are being ignored.

The EPA policy of low priority for me-too registrations and pesticide amendments has and continues to stifle competition and unnecessarily impedes the introduction of improved products to the public. This practice is particularly damaging to the smaller manufacturers and marketers who can't "ride out" long delays in entering the marketplace. Not since 1977 have delays been this bad. Surely, it is not the intent of this committee to foster this kind of disastrous competitive situation. The Agency therefore needs to be redirected in its priorities to properly process me-too applications and amendments to registrations in a timely manner - that is within specifically defined timetables - EPA should not only streamline its present registration process but more importantly, should redirect its registration personnel to the administration of the entire registration process. The administrator should be directed to involve personnel from other programs if necessary to the registration of pesticides so as to ensure fairness in the registration process and the fostering of competition.

CSMA suggests an amendment to Section 3(c)(3) which would require the Administrator to accomplish the registration of all pesticides in the most expeditious manner practicable, which would indicate a priority to applications for products identical or substantially similar in composition to any currently registered pesticide or for amendments to existing registrations. This amendment would also require the administrator:

-to notify the registrants of the above pesticides within 45 days after receiving an application whether it is complete,

-to notify the registrants of the above pesticides within 90 days after receiving a completed application if it has been granted or denied, and

-to notify the registrant of the above pesticides in written form of the specific reasons for denial.

G. Research and Monitoring - A Biological Test Facility

EPA should maintain a biological testing facility at Beltsville, Maryland. During the 98th Congress, Senator Paul Sarbanes (D-MD) introduced S.B. 780, a bill to require that the EPA maintain a facility for the biological testing of pesticides under FIFRA. We support language similar to this bill.

We believe it is appropriate to have one federal laboratory facility that has the capability to provide testing of disinfectant materials and thus avoid conflicts over testing methods and test results.

Without such a laboratory we see the possibility of various states obtaining different test results on the same product and thereby taking different enforcement actions.

V. Conclusion

We all share a common goal that all pesticides are safe and effective for their intended uses and that they do not pose unreasonable risks to man and the environment. A number of the concerns we have noted in our full text today, however, impose an unnecessary economic burden upon our industry and will, as well, deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives. We at CSMA are committed to work with the committee to help resolve these important matters and thereby improve the prospects for passing FIFRA legislation.

Senator HARKIN. I am informed that you have to catch a plane or something.

Mr. ENGEL. Well, I think we are on schedule so far.

Senator HARKIN. Well, I will start with Mr. Engel. I have just one question. You represent the Chemical Specialties Manufacturers Association. You have proposed an amendment to exempt certain workers from training requirements dealing with consumer products. Just identify yourself for the record when you speak.

Mr. MURPHY. John Murphy, director of legislative affairs for CSMA. Yes, Senator, we have, in our comments, suggested that users, commercial applicators, of antimicrobial products and consumer products be exempt from the registration and certification requirements. That is correct.

Senator HARKIN. Who would that be?

Mr. MURPHY. That would be janitors and maids. They would be people who, in fact, would be applying disinfectants in the home.

Senator HARKIN. How about janitors in schools?

Mr. MURPHY. That would apply to those people also.

Senator HARKIN. As I understand it, S. 1516 gives EPA some flexibility to make these decisions. Do you not think it would be wise—I mean you are not going to have every homemaker come in and train or something like that. But I mean when you talk about janitors in school buildings, where they may be applying pesticides, that perhaps might be wise for them to do some training? I am just trying to get a clarification of this.

Mr. ENGEL. I am sorry. I did not recognize when you asked what specifically we were dealing with. The object of this amendment, specifically, is to limit its use to certified applicators other than, for example, the consumer himself in the home or a maid in the home that is using, for example, a drain cleaner. That is a pesticide. Or, in fact, a toilet bowl cleaner, if you will, that is a pesticide. And to be certified and take courses on how to do that.

I think the object is to eliminate the consumer from certification and essentially make it a commercial application effort.

Senator HARKIN. But again let me ask you about the case that Mr. Murphy brought up, which is exactly what I was trying to get at. It seems to me if you have a broad brush stroke on this you do exempt from training certain people like janitors, but that is not your intention to do that?

Mr. ENGEL. A janitor in a school I would look at in some cases probably as a commercial application.

Senator HARKIN. I was just trying to get to that.

Mr. ENGEL. We are trying with this amendment to eliminate some of the absurdity of having the housewife, or a maid or janitor become certified applicators.

Senator HARKIN. I understand that. I just wanted to find out where you were. Mr. Murphy is trying to get my attention over your shoulder.

Mr. MURPHY. Senator, if you would, in the case of the janitor, the exemption that we are looking for is not for the janitor that is applying large quantities of commercial product but the janitor who buys Raid from the same supermarket shelf that the consumer would, and he is asked by his employer to kill a few ants that happen to appear in a classroom or happen to appear somewhere else on the premises, and he uses this can of Raid. Why should he be trained and certified to use this product when the consumer isn't?

We do not ask that he be exempt when he is using for a large part of his responsibility or using commercial quantities, but solely when he applies consumer quantities and consumer products in consumer packages. For antimicrobials and disinfectants we are seeking an exemption for all uses, institutional and industrial, as well as, consumer.

Senator HARKIN. I just wanted to get that cleared up. The only other question I have is that you have proposed a data coordination and synchronization amendment to FIFRA. Could you tell the committee specifically what you are trying to achieve with this amendment, this data coordination and synchronization amendment?

Mr. ENGEL. Mr. Chairman, the object is to prevent duplication of testing at the State level and the Federal level on the same active ingredient. I mentioned that, for example, the State of California has a data call-in process now ongoing. It is not our intention to say that a State like California cannot obtain data, and it is not our intention to indicate that the Federal Government should not have data or fill data gaps.

Our object, though, is to coordinate these efforts between the Federal Government and the States so that, in fact, once an active ingredient is to be called in for reregistration and test protocols are set up, the States and the Federal Government can develop those test protocols together, and the testing can be done at one time.

Senator HARKIN. How long would it take to get all of this accomplished? You could perhaps read the proposal differently since in your proposal the requirements must be quote "identical and concurrent" among all State and Federal agencies.

Mr. ENGEL. No, it would seem to us, Mr. Chairman, to be infinitely better if product *x* active ingredient is going to be called in, that perhaps the States and the Federal Government can get together and decide to have a call-in at one time to start with. The second thing they can do is to have their technical people sit down together and devise the protocols one time for the industry to do the studies.

Now industry is not saying we do not want to do the studies, and we do not want to fill these data gaps, and industry is not saying we do not want to provide the data to States. All we are saying is we would like to do the studies one time and not duplicate them State by State by State, and that is our objective. It is not to say that a State cannot ask for more data than the Federal Government, if they need more data. We are saying that when you are doing the same thing, when they are calling in to fill data gaps on the same active ingredient, by golly, it makes sense to us that they can sit down and establish the same technical protocols to do the studies at one time.

Senator HARKIN. I was not here this morning, but I guess EPA said basically the following. Would a State have the right to impose data requirements beyond Federal requirements, or would this, in fact, be State preemption?

Mr. ENGEL. It is not State preemption, and I just noted a State could ask for additional data beyond that of the Federal Government. All we are doing here is saying when product *x* is called in by a State, and product *x* is being called in by the Federal Government, and they are requiring the same studies, why not get together and set up the same technical protocols to do these studies so we do not have to do them differently and twice?

Senator HARKIN. So the State would have the right to impose data requirements beyond Federal requirements?

Mr. ENGEL. That is correct.

Senator HARKIN. I just wanted to get that cleared up. Would a State be able to require data to be submitted earlier or later than federally required studies? I mean if they said——

Mr. ENGEL. I think that goes to the heart of the protocol.

Senator HARKIN. You want them both the same.

Mr. ENGEL. If, in fact, the State toxicologist and Federal toxicologist get together and set up a protocol and everybody can live with it, the studies are going to be done over the same timeframe. Because a protocol establishes the timeframe for the studies.

Senator HARKIN. Again, I was calling on you because I thought you had a plane.

Mr. ENGEL. Well, I do. I am going to leave at 3:15.

Senator HARKIN. Let me ask Senator Bond if he has any questions, and then we will move on to the other witnesses.

Senator BOND. Let me ask Mr. Engel, you mentioned the California laws briefly with respect to data. Do you and your organization see any impact on consumers or farmers in other States as a result of the California laws which would affect your industry?

Mr. ENGEL. Senator Bond, we know that there are two States in the process of establishing the same laws, New Jersey and Massachusetts. We know there is a discussion now going on in a third State beyond California. Our industry, nor do I believe any industry can continually do studies over and over again State by State. That is why we are basically suggesting as an industry that it can be coordinated and synchronized and the studies can get done in a timely manner. If you do it over and over again I suspect what is going to happen is our industry will just throw up their hands and say we cannot do it because we do not know who is going to ask for the next set of tests that is different.

Senator BOND. Well, is it likely that you would have to forgo sales in the State that imposed those burdens or what would be the impact?

Mr. ENGEL. Yes. I believe that the uncertainty of not knowing what testing is going to be required in one State versus another State on the same active ingredient will cause companies, particularly small companies, to throw up their hands and say we cannot afford to do this.

Senator BOND. In other words, drive them out of the research business?

Mr. ENGEL. Correct.

Senator BOND. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bond. Senator Wilson.

Senator WILSON. Mr. Engel, if I understand what you are saying, it is that you do not object to State standards, and you are seeking simply to minimize a multiple performance on the part of the manufacturers?

Mr. ENGEL. That is correct, Senator Wilson.

Senator WILSON. Obviously, is there in your judgment, to be the devil's advocate, a practical response to the States that come forward with the argument that EPA and the States may not have the same problem, that they may not have the same goal in mind, and that there may be a requirement on the part of a particular State for tests that EPA would not see any necessity for?

Mr. ENGEL. That is fine. We are basically saying if the State of California wants to ask for additional tests and has a reason for asking for additional tests, that is not what we are after here. What we are basically saying, again, is if EPA puts out a data call-in or a reregistration package, and it requires six tests, and the State of California is going to have a data call-in or the same active ingredient and it wants eight tests, the first six are the same as that of EPA's. We are saying, by golly, let us get these toxicologists out in California and the toxicologists at EPA to sit down and develop the protocols necessary for doing the testing for the first six because they are the same tests that need to be done in both cases.

Now, California is saying there are two more tests that we need for special reasons. That is not our argument. We are saying let us sit down and at least coordinate and synchronize the same testing.

Senator WILSON. Have you made that argument to the States, and if so, what response have they made to you?

Mr. ENGEL. We have made the argument in the State of California on reams of paper specifically to CDFA, and we are not getting any responses there because they do not really have to respond. There is no reason to respond. There is no action that requires them to respond, nor is there any reason for the EPA to respond to the other side of the fence because there is no reason to respond. That is why we are asking for this amendment so that there is reason for people to sit down and respond to something that we believe is, honestly, very practical and saves a lot of time and money.

Senator WILSON. So you have not had any direct rejection from the Federal or the State respondents? You just have not had any response?

Mr. ENGEL. They are not responding positively or negatively. That is correct. This morning EPA testified, and although I was not present, I believe Dr. Moore indicated that if this amendment is the way I have just described it, they would have no problems with it.

Senator WILSON. So you are sort of interpleading. You are trying to get everybody into court on the same day.

Mr. ENGEL. True. There is another plus to this, particularly, sir, in your own State. You have testing facilities out there. You also have something like 30 toxicologists out there as part of the CDFA. There would be an opportunity to use the facilities in the State and the State use the facilities of the Federal Government and perhaps save some time and money there as well.

Senator WILSON. Is there any legitimate reason to suppose that if the tests were performed differently, or excuse me, if they were performed not once to satisfy both the Federal and State requirement, but if they were performed separately by the State and then, as you are seeking to avoid, by the Federal Government, that there would be any difference in the result?

Mr. **Engel**. We do not think so. I think that basically the problem is that they are not talking to one another officially to accomplish this end.

Senator **Wilson**. So your amendment seeks to have one test satisfy two different agencies?

Mr. **Engel**. One protocol, that basically says if I need to do a chronic toxicity test on hamsters, and the other State says, well, we do not want them on hamsters, we want them on rats. Then let these toxicologists sit in a room and decide what they should have as these chronic tests and come up with a decision that is scientifically sound.

You asked, Mr. Chairman, whether this was preemption. I think the only preemption in this amendment might be the preemption of bad science with good science. I think nothing but good could come from a series of toxicologists sitting in the same room and hammering out the same protocol.

Senator **Wilson**. Thank you.

Senator **Harkin**. You are not really accusing the States of having bad science, are you?

Mr. **Engel**. No, I am not even indicating that. That is not my point. My point is perhaps three or five heads are better than one.

Senator **Harkin**. Thank you very much.

Senator **Wilson**. Excuse me, Mr. Chairman. What you are saying, in effect, you are not accusing the States of bad science. You are saying that the States could perform the tests and satisfy the Federal requirement as well as their own?

Mr. **Engel**. Correct.

Senator **Harkin**. Thank you, Senator Wilson. Thank you very much, Mr. Engel.

We move ahead now to the Chemical Producers and Distributors Association, Mr. Shockey and Mr. Burchett. I have a couple of questions.

On this issue of data compensation, which we got all hung up on last year, and which looks like we are going to get hung up on again this year, perhaps. I hope not. But I hope we can meet some reasonable compromises on this. Let me just ask you this which is a very simple and straightforward question. Are there big firms and small firms on both sides of this issue? I guess some people have tried to characterize this as a big versus small fight, but that is not really it; is it? I mean there are big firms and small firms on both sides of this; is that right?

Mr. **Shockey**. Yes, there is more of one than the other, but that is true. There are small research firms and large research firms.

Senator **Harkin**. On both sides of this?

Mr. **Shockey**. Right.

Senator **Harkin**. Why do you believe that the current arbitration process is unfair?

Mr. **Shockey**. It restrains trade.

Senator **Harkin**. Pardon?

Mr. **Shockey**. It is totally restraining trade. It is a restraint of trade the way it is now. It is impossible for another company, sometimes even small or large to enter a generic market. We are being asked to pay 5 and 10 times and 20 times what real data costs.

Senator HARKIN. That is an example that you gave in your testimony?

Mr. SHOCKEY. Right. Our company has been in arbitration on one compound with Du Pont for 21 days. We have had 21 days of arbitration here in Washington, and we have only heard Du Pont put on their side. We have not been heard yet. We will be heard in December. That is costing us, I think just for the arbitrators and for the room, about $2,000 a day plus we have lawyers from Washington, lawyers from Memphis, Tennessee, and we will run in this arbitration in legal fees alone, it will cost our company $750,000.

Senator HARKIN. So you would rather have this whole thing spelled out a little bit more clearly in the data compensation section of the FIFRA bill?

Mr. SHOCKEY. Right. Most of the data compensation they are asking for is data for research that is in many instances obsolete. It is more than 15, 17 years old. It would not be acceptable today under today's protocol. They are asking for the cost that it would cost to generate the data today, at today's costs. They are also asking for a market value for that data. In other words, the data, just because it might take me 2 or 3 years to generate that data, they want me to pay them $50 million for $2 million worth of data, or $1 million worth of data.

Senator HARKIN. Well, we would be better off if we had more current health and safety data than something that was 15 years old; right?

Mr. SHOCKEY. Certainly, but that is another problem. You have one problem now of restraining trade. If you want new data and more data, that is something else. But right now the products are being sold are 5, 10, 50 million pounds of some of these products sold, and patents have expired 3 and 5 and 10 years ago, and you still only have one or two people in the market.

Senator HARKIN. Mr. Burchett, if I could ask you a question. First of all, I just want to compliment you for an attempt at a very constructive compromise. I think you have approached this in a very constructive manner, and I believe there are some things here that we might want to incorporate in this data compensation section.

As I understand it, the amendment that you want would basically permit this manufacturer of the generics to conduct the testing at any time they could do the testing, so long as nothing was done until the data, until the patent ran out on it?

Mr. BURCHETT. That is correct.

Senator HARKIN. To do the testing on it. Accumulate the data, for example.

Mr. BURCHETT. Right. In other words, be able to go ahead and conduct the tests, turn them in to EPA to obtain a registration at any time prior to the patent, but under no circumstances would a company be allowed to sell any product until the patent was expired.

So we see both ways that they are deserving of additional patent life, but at the same time it would seem as long as one can go out to the full term of the patent, there should not be an objection to doing the test ahead of time. You still cannot sell the products so we feel it is a just way to go.

Senator HARKIN. Mr. Early, do you have any problems with that?

Mr. EARLY. I am sure I do, Mr. Harkin. Most people would have been surprised if I did not say that. I am going to make just a general comment, and then Mr. Hagaman will make some more detailed comments, if he may here. But let me just remind the committee here, and also for our friends on the other side, that we reached some very substantial agreements last year on this issue, and we are prepared to stand by the agreements that were arrived at last year. We are prepared to stay there right now, and we are not willing to back away from the agreement which was a concession on our part.

Now I will let Mr. Hagaman perhaps expand on that.

Senator HARKIN. Well, the answer to this question, because I am interested in this, and why it is wrong to go ahead and allow the testing to meet the requirements of FIFRA or FDA as long as they were not able to sell those, as long as they could do the testing beforehand? What is wrong with that proposal? I thought it was a very constructive proposal that was just made, and I am trying to find out why you would be opposed to it.

Mr. EARLY. Really what this goes back to, and I am not an attorney—I might have to have the counsel behind me get into this—but it goes back to a decision made by the courts some time ago called the *Roche/Bolar* decision that was referred to by Mr. Shockey. That decision of the court said that one could not get involved in that process before a patent ran out. That was something that was part of the patent process that has been available to us for many, many years.

What we are seeing here is that in the compromise of last year we agreed to back off from that situation and allow at least 2 years of testing before, but we were not willing to give the whole apple away. So we were allowing some period of time for testing before the patent went out, a total of 2 years, but not the whole *Bolar/Roche* decision, giving that up.

Can you add to that, John?

Mr. HAGAMAN. Mr. Chairman, if I could, I think it is important to note that with all of these products it is many years into the patent life before they become commercial, and that is the whole issue of patent term restoration and the proposals to add some patent life to compensate for the time that is necessary to get into the market because a basic manufacturer does not have 17 effective years of patent life.

I think many of the proposals, which differ from what the compromises that were reached last year, link together further compromises on data compensation in return, in effect, for support of patent term restoration.

In our view, the fallacy of that is that a basic manufacturer will not receive any benefit from patent term restoration for 17 years. That is many years into the future. The compromises on data compensation are today. So we are being asked, in effect, in the compromises to sacrifice today and tomorrow for something we may get 17 years from now.

Senator HARKIN. Mr. Burchett.

Mr. BURCHETT. I might make a comment. First off, the amendment we have requested here has no ties whatsoever to data compensation, point one. Point two, the concern would be is that if you extend or add the PTR, the 5-year life, on and do not overrule the *Bolar* decision, meaning that we would not be able to test until the patent has expired, then go in at that point in time when I legally could perform my test and obtain my label. What, in effect, that does is give a patent life to that patent holder of 27 to 29 years for a patent. I do not think that is just.

To give 5 years added on, that is, but I still fail to see why we would not be able to test prior to that.

Senator HARKIN. That is what I was understanding. That is what I thought was constructive.

Mr. BURCHETT. Right.

Senator HARKIN. You supported the 5-year patent.

Mr. BURCHETT. That is correct.

Senator HARKIN. You supported that, and all you said is, that basically, you should be allowed to go ahead and test at any time to meet the regulatory requirements, but you would still not be able to engage in any commercial activities on that until the extension of that patent life which would be that extra 5 years; right?

Mr. BURCHETT. That is correct.

Senator HARKIN. I do not understand what the problem is with that.

Mr. EARLY. Mr. Chairman, may I comment? Let me comment. Maybe one of the differences we are looking at, Mr. Harkin, is that I think we would be prepared to look at the *Bolar* decision and some things in that direction on a number of years provided it was tied to patent term restoration.

You see Mr. Hagaman tried to point out to you that it was done in tandem with one another. He has pointed out the difference. Patent term restoration gives us something out there 17 years. Repeal of *Bolar* gives them something immediately here up front. Now we are prepared to deal with the *Bolar* time thing, I suspect, as long as you want to tie, give us patent term a little quicker in the process. Does that help at all? Perhaps it confuses things.

Mr. BURCHETT. I see what he is saying, Senator.

Senator HARKIN. I do not understand it. I thought I understood the *Bolar* decision, but maybe I did not.

Mr. BURCHETT. What I think he is saying is that a product that is going to come off of patent in the next couple years, say 5 years from now, assuming this all passed, and a patent is going to come off next year, I would be allowed to start testing on that product today. He is saying for the 5 years that he is being given he does not get a reward for that until after the 17 years that he would automatically get. It goes way on out. So he is saying you get a reward now. I do not get a reward for a long time in the future. And I appreciate that, but I think that is a little off base as we have been told several times, because of the reduced patent life, they have products inside the laboratories they cannot commercialize because of reduced patent life.

Senator HARKIN. They have what?

Mr. BURCHETT. Products and numbered compounds that they simply cannot justify economically to even develop because of the reduced patent life. We are saying by giving them that 5 years they may have some very good compounds, helpful to us all, that now they can afford to bring out of the laboratory. Therefore, they are getting some benefit now, and it is not all in the future.

Senator HARKIN. I do not want to get in a game of ping pong here. Yes?

Mr. HAGAMAN. Mr. Chairman, let me make one attempt to bring some clarity to it. Hopefully, I will. I think that maybe one way to look at it is, that, if we looked at it on a specific product, product-by-product basis, for a given product or compound, which received the benefit of PTR, and therefore extended patent life, we as the industry, I believe, would be prepared to look at repealing *Bolar*.

The problem is if we deal with it in its entirety what happens is that products, if we deal with all products at once, repeal *Bolar*, as an example, then products which are coming off patent in the next year or 2 years or 3 years then gain the benefit of the repeal of *Bolar*, and the research based companies do not get any benefit until 17 years from now for the new products. If dealt with on a product-by-product basis, then I think it makes sense.

Senator HARKIN. Because of the *Bolar* decision they would not have been able to have done any of this testing. So I mean it comes off in the next couple of years. Well, they have not been doing any testing anyway unless they have been breaking the law.

Mr. HAGAMAN. True. But for a product which is in the process of coming off patent in the next few years, then the benefit would be gained where no benefit to the research based industry would be achieved for many years.

Mr. STICKLE. Mr. Chairman, can I add a comment to this? What we are really talking about is that the basic manufacturers are having 17 years for a patent. They would like an additional 5 years of patent extension which would give them a total of 22 years. In addition to that, unless one were to roll back the *Bolar/Roche* decision, we have to remember that it takes 5 to 7 years——

Senator HARKIN. Testing.

Mr. STICKLE [continuing]. Testing.

Senator HARKIN. That is right.

Mr. STICKLE. So you add that to it, and we are looking at 27 to 29 years.

Senator HARKIN. That is right.

Mr. STICKLE. And that is de facto additional patent restoration. So when they say they want 5 years of patent restoration, they are not really meaning 5 years. They want 5 years patent restoration and 5 more years of *Bolar/Roche* protection. They are asking for 10 years, and what we are suggesting, and I am in agreement with my friend from ConAgra, is that, if you give them the 5 years of patent term restoration, you should not give them another 5 years of the *Bolar/Roche* decision because then they wind up with 10 years patent extension.

Senator HARKIN. I have some other questions. I feel like I am taking all the time. Do you want to jump in on this?

Senator BOND. I am following you through this.

Mr. EARLY. Let me make one additional comment to correct one little thing that Dr. Stickle has said here. He has implied that I got 17 years of patent life, and then I get another 5 and another 5, or something like that. Patent term extension, keep in mind, is to restore that amount of 17 years of patent life that you lose, that you lose through the testing process.

You do not get another 5 years added on top of that. You are restoring. You restore what you lost to this testing process. You should understand that.

Senator **Harkin**. Well, I will think about it. [Laughter.]

I still have a hard time because this sounds like a reasonable compromise, and I am going to have to think about it. Senator Bond.

Senator **Bond**. Just to get back in some more basic areas. I do not know if you were here this morning, but there was some testimony that all synthetic chemicals should be banned, and some of the witnesses took that approach. Do you have any comments, and I will start with Dr. Early, on how that might impact the production of food, the availability and the cost?

Mr. **Early**. Thank you, Mr. Bond. I would be delighted to make a comment or two here. First of all, I would take issue with Mr. Nader. You know he is trying to imply that there are differences between natural versus man made chemicals. I think you would have a tough time convincing a chemist or people who understand the processes that there is any difference between man made or natural chemical.

The answer to your question is if you were to eliminate all the products in the marketplace today that contained quote "synthetic" chemical, you are going to eliminate most of the products on the marketplace today, the herbicides, insecticides, fungicides, almost everything in the marketplace.

Now, we could extrapolate that down to a complete loss of the apple crop, half the cotton, a good part of the wheat and the soybeans. You could come up with some pretty large numbers in a time when agriculture is in big trouble. So I think it is totally unrealistic to expect one to really entertain that thought?

Senator **Bond**. Any of the rest of you care to comment on that? We would welcome your comments to include in the record.

Mr. **Shockey**. I think it would be like giving up our medicines. It would be almost the same parallel as that.

Senator **Bond**. To carry out that thought?

Mr. **Shockey**. Right.

Senator **Bond**. Explain that to us.

Mr. **Shockey**. Well, I think that the pesticides are as important to us as medicines are today, and some of them are synthetically made. I do not think we would think of giving those up. But I think in the productivity of our food and our health, too, that pesticides are extremely important and properly used, we do not believe there is a risk.

Senator **Bond**. I believe it would be appropriate, Mr. Chairman, if any of the witnesses want to provide further comments on that for the record so that we might have their views, would that be accepted?

Senator **Harkin**. Sure would. Absolutely. The record will stay open for additional views.

Senator **Bond**. Let me ask the members of the panel who are still here if they have any comments on the question I asked Mr. Engel before he left. Do you see any impact on producers and consumers in other States from the imposition of laws such as the law in California? Would there be any impact, and if so, what?

Mr. EARLY. Mr. Bond, I think any time that you add to the complexity of this business that we are in, whether it is at the Federal level or the State level, you must understand that those costs are going to be passed along to the farmer and ultimately to the consumer, to the extent he can.

Mr. Engel spoke to it, and I think very well. There are some States out there entertaining some of the similar situations that we see in California. So yes, there could be some impacts out there. I am not sure that I know exactly what they would be. Perhaps Mr. Hagaman could add to that.

Senator BOND. Mr. Hagaman.

Mr. HAGAMAN. Yes, there would be impacts. I believe that the first place that you would see the impacts, or are in fact already seeing the impact, is the increased cost of being able to be in the pesticide business is in the area of minor crops.

What you are seeing now is research done on major crops, not very much on minor crops, so the problems of minor crops, as this compounds itself, will be the products that will be applicable to them and will be spinoffs of what are available for major crops. So the minor crops are going to be the first and the things that will be hit the hardest.

Senator HARKIN. Thank you. Any other comments? Any of you wish to comment? Dr. Stickle.

Dr. STICKLE. Senator, I would like to associate my comments with Mr. Engel, who testified before, because what we are really looking at is trying to eliminate the duplication and unnecessary testing so that you wind up doing one set of tests in one State and another set of tests for another State and another set of tests for another State.

The net result is that we keep adding to the cost of pesticides and what we are looking at is consumers, farmers, ranchers, users winding up for a higher price as far as pesticides are concerned.

I think you can actually get the job done and close the existing data gaps faster if you have some coordination and some synchronization between EPA and the States, and especially where you are getting into minor-use products. I think it is very important there, and I would agree with what Mr. Hagaman said as far as that is concerned.

Senator BOND. Thank you. Mr. Burchett.

Mr. BURCHETT. We would only say, we concur with the rest. We have already anticipated the problem for example, in California, in just this past year, although we are not into technical materials like a research type company but on our end use products, we have already pulled 60 of them out of California.

We just had one last week I pulled out of Michigan for the carrot growers. We would like to be of some help, but with the data requirements and seeing what is coming down the way, you are forced into a situation of saying I am sorry, and this particular one happened to simply be because it was mineral oil and because mineral oil came up on the hit list in California. We are just going to back off and say here are some other ways that you might be able to address your problem. But we have canceled that label.

We see more and more of that. That is going to happen as the registration fee issues, if nothing else, come up. Many products are going to go. The smaller ones may go. There will be quite an impact.

Senator **Bond**. The impact would be, then, on producers of minor crops in other States, who because of the restricted market in those States, which have more expensive processes, they would not go forward with research or with production of certain pesticides. Is that right?

Mr. **Burchett**. Well, I think it is a combination, Senator Bond, that can have a snowball effect which started in California. The next State, as I recall, to rolloff into that type of situation is Arizona, and then the other two States—what, Connecticut and Massachusetts, the others that are coming. Pretty soon as you start eliminating States, pretty soon the amount of profit that you can generate to hold that compound, as it is eroded pretty soon you just cannot justify holding that product any longer, and we can see that as the ball starts rolling.

Senator **Bond**. Thank you, sir. Mr. Chairman, I thank you.

Senator **Harkin**. Thank you, Senator Bond. Apropos or appropriate to this point, I have a letter which I would ask unanimous consent to introduce in the record at this point from James B. Grant, executive secretary of the National Association of State Departments of Agriculture, opposing H.R. 2869, which is the synchronization amendment.

[The material follows:]

1616 H Street, N.W. • Washington, D.C. 20006 • (202) 628-1566
James B. Grant, *Executive Secretary*
Robert Amato, *Assistant Executive Secretary*
Gordon C. Miller, *Administrative Assistant*

July 21, 1987

Honorable E de la Garza
Chairman
Committee on Agriculture
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In 1986, the National Association of State Departments of Agriculture supported H.R. 2482, a bill designed to overhaul the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). We continue to support FIFRA legislation in 1987 which is basically the same as that passed by the House last year.

The FIFRA legislation of 1986 was reached after two years of discussion between consumer groups, industry, states, environmentalists, producers and others. Many hours were spent before all sides "signed off" on the bill. Our policy is to continue to support similar legislation. Any major changes would cause us to reassess our position relative to proposed legislation. We, along with many other organizations, labored hard and long to reach the compromise legislation acted upon the House last year. We compliment the members and staff in guiding this bill through the legislative process. It's not perfect, but it is supportable. We urge you not to abandon the bill you passed, but to give every consideration to the same legislation. If it was acceptable in October of 1986, why is it not acceptable in July of 1987?

In regard to H.R. 2869, a bill that purports to coordinate and synchronize pesticide data requirements, we are totally opposed. It is another attempt to preempt states' rights, but under another guise. We will continue to oppose this type of legislation, and respectfully urge you not to consider this further attempt to preempt the states in your markup of pending FIFRA legislation.

We fully understand and support the dedicated efforts of the committee to monitor and, when necessary, to amend FIFRA for the benefit of agriculture and protection of the consumers of food products produced in the United States. We pledge our continued cooperation in your efforts.

We look forward to working with you and the committee on the passage of meaningful FIFRA legislation during the 100th Congress.

Sincerely,

James B. Grant

James B. Grant
Executive Secretary

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Senator **Harkin**. Mr. Early, before we all leave, I have to go to another meeting, I think Senator Pryor is going to be kind enough to take over here, I want to get into this ground water thing with you a little bit. As you know, Iowa has recently passed a strong ground water protection bill that was passed quite handily in the State, signed by the Governor. We have had some unique problems in the State of Iowa with that.

As you know that bill did not really contain standards. Have you had a chance to look at the Iowa ground water bill?

Mr. **Early**. Mr. Harkin, we have been very much involved with the Iowa bill. We are very familiar with it. Counsel behind me is extremely aware of what is going on out there.

Senator **Harkin**. Just forthrightly, were you supportive of the final bill that came out?

Mr. **Early**. The final bill was one, as we say, we recognize we could live with it.

Senator **Harkin**. You could live with it.

Mr. **Early**. We wanted some things, obviously, that we did not get in that situation out there, but it was something in the final analysis we said we could live with. But I just heard yesterday, I am sure, that is going to be revisited again next year by the Iowa legislature. That is what I have heard anyway.

Senator **Harkin**. It may be. It may well be. I do not know.

Mr. **Early**. If you have some specific questions, our specific reaction to that, our counsel would be glad to comment on it.

Senator **Harkin**. Well, this whole idea of having a standard came up, and then it was taken out. So there are no standards. They were concerned that if you have a standard, then people can pollute up to that standard, and they wanted to keep it as low as possible. In your testimony, you wanted to use what is called the maximum contaminant level, MCL.

Mr. **Early**. That is correct.

Senator **Harkin**. As a standard?

Mr. **Early**. Yes.

Senator **Harkin**. Now correct me if I am wrong, but I understand that is based upon, maximum contaminant level is the standard that is sort of based upon cleaning up damage that has already been done.

Mr. **Early**. Let me get my expert behind me to respond to that, Mr. Ferguson.

Senator **Harkin**. Get your expert.

Mr. **Ferguson**. The maximum contaminant level is the level that is used in public drinking water supplies here in the United States for the safe level for all kinds of contaminants, pesticides, and other kinds of organics. It is used in the House bill and also in the Senate bill to a lesser extent as the trigger for action.

Senator **Harkin**. But you are saying that ought to be the standard in the bill?

Mr. **Ferguson**. Well, certainly the standard for drinking water. That just makes common sense.

Mr. **Pryor**. Could you repeat that answer, please? Senator Harkin, could he repeat that answer?

Mr. **Ferguson**. The maximum contaminant level is the level of purity for water, and what we are saying is a farmer in Iowa should have the same standard of purity for his water as for people here in Washington, DC and elsewhere in the country.

We are applying it to drinking water.

Senator **Harkin**. Could I talk about the chart on page 6 in your prepared statement that you have? First, I need to clarify a few points. First of all, the chart lumps carcinogens and noncarcinogens together. But in fact they are treated differently in the law. [See page 159 for the chart.]

For noncarcinogens, the standard in the House bill and S. 1419 are the same. That is the MCL and the MCL goal are the same. The difference is in the way carcinogens are treated. In the Safe Drinking Water Act MCL goals are set at zero. S. 1419 does not go that far. Instead, the bill allows the use of MCL as long as it is not any higher than a one-in-a-million risk.

That is S. 1419. This is the level of risk that the National Academy of Sciences' report said was acceptable for pesticide residues in food. So my question to you, Dr. Early, or to—I am sorry.

Mr. **Ferguson**. I am Scott Ferguson, general counsel for NACA.

Senator **Harkin**. Mr. Ferguson, my question is this: do you advocate the use of a higher level of risk for exposure to cancer than the one-in-a-million risk?

Mr. **Ferguson**. We are advocating using the MCL which is the standard used everywhere in the country, whatever that standard is for carcinogens and noncarcinogens.

Senator **Harkin**. Well, in the Safe Drinking Water Act, MCL's are set at zero.

Mr. **Ferguson**. If that is the case. We are representing MCL's should be used, maximum contaminant level.

Senator **Harkin**. For carcinogens at zero.

Mr. **Ferguson**. If that is the case.

Senator **Harkin**. But S. 1419 allows the use of MCL no higher than one in a million risk. Is that okay with you?

Mr. **Ferguson**. That is your testimony. I do not know.

Senator **Harkin**. No. But is that okay with you?

Mr. **Ferguson**. I think we are digressing. The MCL, if you are talking about the Safe Drinking Water Act is the standard for carcinogens and noncarcinogens, whether it is set at zero or something above zero. That is the safe level that our Government has determined for contaminants in our drinking water. And we can live with that.

Senator **Harkin**. Well, I guess what I want to know is that our bill has a difference between carcinogens and noncarcinogens. In S. 1419, the bill allows the use of an MCL as long as it is not any higher than a one in a million risk. That is for carcinogens, not for everything lumped together.

I am asking you if that is a level that you could support?

Mr. **Ferguson**. Let us be clear. Over on page 4 of the prepared statement there is a diagram. [See page 157 for the diagram.]

Senator **Harkin**. Page 4 of your prepared statement?

Mr. **Ferguson**. Yes. What your bill does, Mr. Harkin, is to set a zero or close to zero level from the ground water table down. As you know, in agriculture sometimes the ground water table is very close to the surface, within inches.

Some cases it is in the root zone. In other words, in the areas where that would be, such as Florida, the Delta and some other places, you could not use agricultural chemicals because you could not get to zero. Upon application, you would be immediately above zero.

So that would mean that modern agriculture in a good portion of our country would end. You simply cannot apply that across the board in all ground water. And we are saying with respect to drinking water, and you will see where that is indicated here on the chart, we are willing to live with the MCL, maximum contaminant level, which everyone lives with.

And we are willing to take whatever steps are necessary not to contaminate drinking water. But as to other areas, and they are indicated there, we are willing to live to the standard that it would not cause unreasonable adverse effects.

That is the standard of FIFRA. That would allow farming to continue in those areas. That is very reasonable, I think.

Senator **Harkin**. S. 1419, let me read it for you, Mr. Ferguson. It says, "the maximum contaminant level has been set at a level which assures," et cetera, et cetera, "that concentrations of the pesticide in drinking water will not present more than a negligible risk of chronic adverse health effects with an adequate margin of safety for groups of sensitive individuals and other subpopulations." I understand that is one in a million.

That is a term of art. "Negligible risks" means one in a million. And I still have not gotten from you if that is acceptable to you, the language of S. 1419? Is that not acceptable?

Mr. **Ferguson**. From what section are you reading?

Senator **Harkin**. This is on page 33. Do you have the bill?

Mr. **Ferguson**. I do not have the bill, but you can give me the section.

Senator **Harkin**. Well, sure I will get it for you. It is section 1429, paragraph 2(B)(ii).

Mr. **Ferguson**. I believe I have the section. But where are you referring now?

Senator **Harkin**. Section 1429 is "ground water residue guidance level—(a) Requirement." Paragraph 2(B) says, "notwithstanding the provisions of subparagraph (A), the Administrator may set the ground water residue guidance level for a pesticide at a level equivalent to the maximum contaminant level for such pesticide if," and then what I read, if it will not present more than a negligible risk.

Mr. **Ferguson**. Well, what you are reading as you may know, is what the Senate bill does to establish a goal, an ideal goal, which is for carcinogens zero. And then provides an exemption, which you are reading, which is a very narrow exemption.

In essence, Senator, what your bill does is to set the standard for all ground water at zero or close to zero. And then provide a very narrow exemption for places where it can be the MCL.

It is much more reasonable, it seems to us, to use the MCL concept, which normally applies to public drinking water supplies, to drinking water, not to ground water generally. If you are going to apply it to ground water generally, as it is done in the House bill, use it as a trigger, to require the Agency to look at the risk-benefit in those situations.

Senator **Harkin**. Well, I do not see why it is narrow. It seems to have it right there.

Any questions on the ground water bill? Anything else before we call a halt to this panel?

Mr. **Early**. I think you can understand why I called counsel to the table to discuss the ground water issue, Mr. Harkin.

Senator **Harkin**. Yes. I am going to have to call my own counsel here too. Thank you all very much.

Mr. **Early**. Thank you.

Senator **Harkin**. I am going to call the next panel which is Rick Hind, environmental lobbyist, U.S. Public Interest Research Group; David Baker, political director, Friends of the Earth; Angel Dominguez, president, Committee in Support of Agriculture Workers; Franci Livingston, staff attorney, Public Citizen's Congress Watch; Michelle Meier, counsel for government affairs of the Consumers Union; and Jay Feldman, national coordinator of the National Coalition Against the Misuse of Pesticides.

I am sorry. I apologize to you. I have just made a slight mistake because I did not read my notes correctly. We do have one witness that I have to call before this panel. But I will tell you what, if the two of you in the center, Ms. Livingston, and who is next to you on your right, Mr. Dominguez.

If the two of you would vacate your chairs, I would like to call James Aidala, specialist in environmental policy of the Congressional Research Service, and Senator Rudy Boschwitz, our distinguished colleague from the State of Minnesota. So I apologize to you. I just did not read my notes right.

Senator Boschwitz is with the U.S. Senate and Mr. Aidala is a specialist in environmental policy. He is with the Congressional Research Service of the Library of Congress.

Senator **Pryor** [presiding]. I am Senator Pryor from Arkansas, and I am going to take over from Senator Harkin for a moment.

Senator **Boschwitz**. What was the name?

Senator **Pryor**. We will talk about that later, but I am going to receive the testimony from these two witnesses. Senator Harkin has to go to the Committee on Appropriations for a meeting, and I think he will be back shortly. So Senator Boschwitz, would you like for your friend to go first, or would you like to?

Go ahead, Rudy.

STATEMENT OF HON. RUDY BOSCHWITZ, A U.S. SENATOR FROM MINNESOTA

Senator **Boschwitz**. Thank you, Mr. Chairman. I think I will proceed first and I appreciate the opportunity to address the committee, and I thank the witnesses who have temporarily abandoned their posts here in order to allow me to do so.

Mr. Chairman, I appreciate this opportunity to address the committee. I have introduced S. 1427, which I hope will become an amendment to the Federal Insecticide, Fungicide, and Rodonticide Act. This legislation would cancel outright the registration of certain cyclodienes.

Cyclodienes, Mr. Chairman, are chemicals used in termite control. These termiticides which include chlordane, heptachlor, aldrin and dieldrin, were banned for agricultural uses in the 1970's, but were given special status allowing continued use for termite control. Evidence now exists that these termiticides are harmful to human health, and are likely to present a substantial carcinogenic risk. We know that acute and chronic exposures to these termiticides are the direct cause of headaches, blurred vision, seizures, and involuntary muscle movements.

In 1974, Mr. Chairman, when EPA banned the use of these chemicals for most agricultural uses, the Agency knew that cyclodienes persisted in the environment for long periods of time and could accumulate in animal and human tissues. Knowing what we know about cyclodienes, one wonders why these chemicals are still registered by the EPA and widely used by the pest control industry? There are two possible reasons: First, until recently, EPA agreed with industry's claim that no effective or economical alternatives existed to control termites, and secondly, that if applied correctly, cyclodienes present no great health risk. So that is why they were continued in usage.

If these are indeed the reasons, Mr. Chairman, it seems to be leaving a great deal to chance, particularly in the application aspect of it, especially when so much is at stake. In the past, cyclodienes accounted for over 90 percent of all termite treatments. Fortunately, a change to alternative chemicals, such as Dursban is now occurring, particularly in New York, New Jersey, Virginia, California, Oregon, and Georgia. We do not have termites, Mr. Chairman, in Minnesota. It is too cold, but I will get to that in due course.

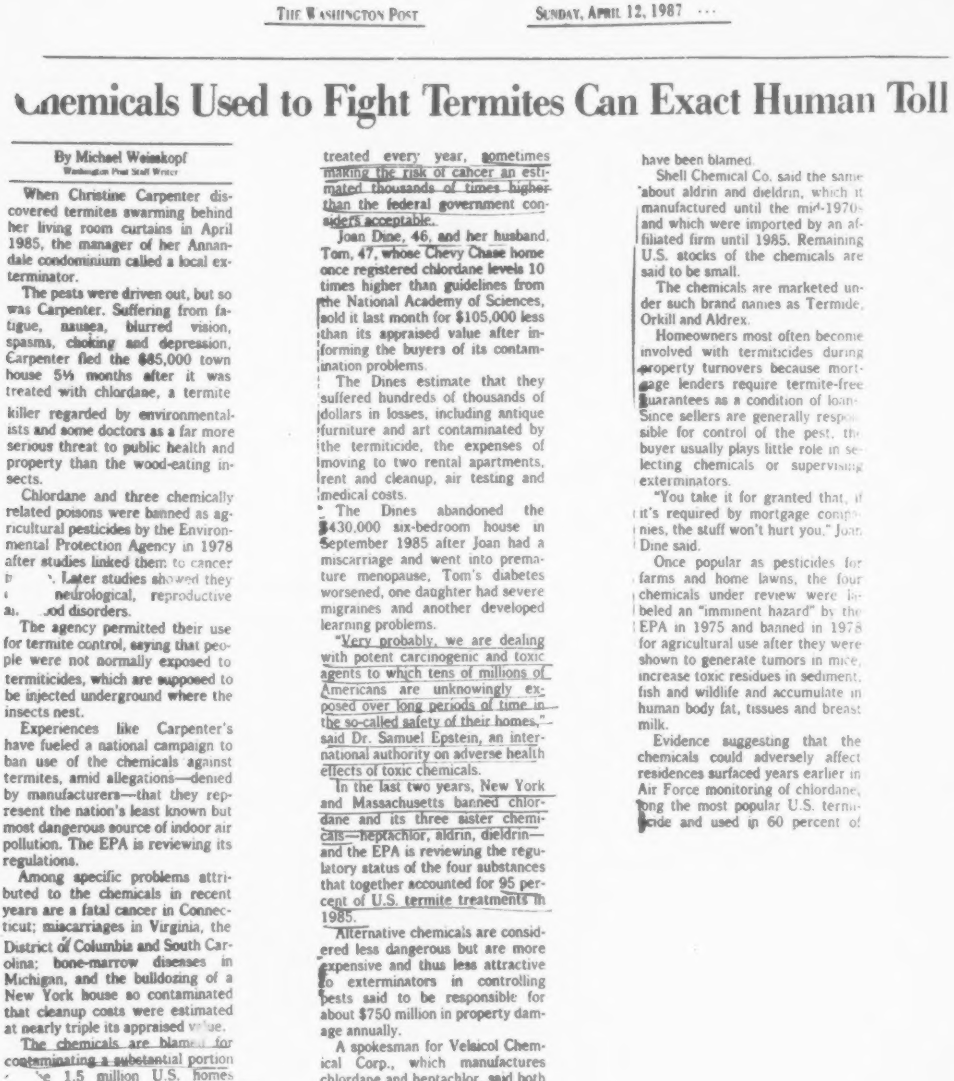
Mr. Chairman, while I am somewhat uncomfortable going outside the chemical registration review system as established by FIFRA and implemented by the EPA, I do so because the current system is too cumbersome to effectively deal with this problem. EPA is approaching the end of its preliminary studies on chlordane. If they announce the cancellation of registration for cyclodienes, a 2- to 5-year process of a review begins, during which time the chemicals can still be used, meaning hundreds of thousands—perhaps millions of Americans will be put at risk. Surely the number would be probably in the millions. While some will argue that we should not legislate the cancellation of a single chemical group, what else are we to do in the face of a 10-year history that demonstrates both the danger of these termiticides and the inability of the Agency to act swiftly?

Too many lives have been lost and too many homes have been contaminated to allow the continued use of cyclodienes.

Mr. Chairman, at this point I would like to ask unanimous consent that an article from the Washington Post dated April 12, 1987, be entered in the record.

Senator PRYOR. Without objection.

[The material follows:]



THE WASHINGTON POST SUNDAY, APRIL 12, 1987 ...

Chemicals Used to Fight Termites Can Exact Human Toll

By Michael Weisskopf
Washington Post Staff Writer

When Christine Carpenter discovered termites swarming behind her living room curtains in April 1985, the manager of her Annandale condominium called a local exterminator.

The pests were driven out, but so was Carpenter. Suffering from fatigue, nausea, blurred vision, spasms, choking and depression, Carpenter fled the $85,000 town house 5½ months after it was treated with chlordane, a termite killer regarded by environmentalists and some doctors as a far more serious threat to public health and property than the wood-eating insects.

Chlordane and three chemically related poisons were banned as agricultural pesticides by the Environmental Protection Agency in 1978 after studies linked them to cancer i[illegible]. Later studies showed they [illegible] neurological, reproductive a[illegible]ood disorders.

The agency permitted their use for termite control, saying that people were not normally exposed to termiticides, which are supposed to be injected underground where the insects nest.

Experiences like Carpenter's have fueled a national campaign to ban use of the chemicals against termites, amid allegations—denied by manufacturers—that they represent the nation's least known but most dangerous source of indoor air pollution. The EPA is reviewing its regulations.

Among specific problems attributed to the chemicals in recent years are a fatal cancer in Connecticut; miscarriages in Virginia, the District of Columbia and South Carolina; bone-marrow diseases in Michigan, and the bulldozing of a New York house so contaminated that cleanup costs were estimated at nearly triple its appraised value.

The chemicals are blamed for contaminating a substantial portion [illegible]e 1.5 million U.S. homes treated every year, sometimes making the risk of cancer an estimated thousands of times higher than the federal government considers acceptable.

Joan Dine, 46, and her husband, Tom, 47, whose Chevy Chase home once registered chlordane levels 10 times higher than guidelines from the National Academy of Sciences, sold it last month for $105,000 less than its appraised value after informing the buyers of its contamination problems.

The Dines estimate that they suffered hundreds of thousands of dollars in losses, including antique furniture and art contaminated by the termiticide, the expenses of moving to two rental apartments, rent and cleanup, air testing and medical costs.

The Dines abandoned the $430,000 six-bedroom house in September 1985 after Joan had a miscarriage and went into premature menopause, Tom's diabetes worsened, one daughter had severe migraines and another developed learning problems.

"Very probably, we are dealing with potent carcinogenic and toxic agents to which tens of millions of Americans are unknowingly exposed over long periods of time in the so-called safety of their homes," said Dr. Samuel Epstein, an international authority on adverse health effects of toxic chemicals.

In the last two years, New York and Massachusetts banned chlordane and its three sister chemicals—heptachlor, aldrin, dieldrin—and the EPA is reviewing the regulatory status of the four substances that together accounted for 95 percent of U.S. termite treatments in 1985.

Alternative chemicals are considered less dangerous but are more expensive and thus less attractive to exterminators in controlling pests said to be responsible for about $750 million in property damage annually.

A spokesman for Velsicol Chemical Corp., which manufactures chlordane and heptachlor, said both are safe if properly applied by exterminators and do not cause serious health problems for which they have been blamed.

Shell Chemical Co. said the same about aldrin and dieldrin, which it manufactured until the mid-1970s and which were imported by an affiliated firm until 1985. Remaining U.S. stocks of the chemicals are said to be small.

The chemicals are marketed under such brand names as Termide, Orkill and Aldrex.

Homeowners most often become involved with termiticides during property turnovers because mortgage lenders require termite-free guarantees as a condition of loans. Since sellers are generally responsible for control of the pest, the buyer usually plays little role in selecting chemicals or supervising exterminators.

"You take it for granted that, if it's required by mortgage companies, the stuff won't hurt you," Joan Dine said.

Once popular as pesticides for farms and home lawns, the four chemicals under review were labeled an "imminent hazard" by the EPA in 1975 and banned in 1978 for agricultural use after they were shown to generate tumors in mice, increase toxic residues in sediment, fish and wildlife and accumulate in human body fat, tissues and breast milk.

Evidence suggesting that the chemicals could adversely affect residences surfaced years earlier in Air Force monitoring of chlordane, long the most popular U.S. termiticide and used in 60 percent of household treatments. The Air Force first tested for chlordane residue in 1972 after occupants of military-base housing in Dayton, Ohio, complained of unusual odors.

Chlordane was found in air samples of 80 percent of the 1,500 housing units tested in the mid-1970s, prompting an Air Force request to the National Academy of Sciences to assess health risks of the chemical and its three sister termiticides.

The academy responded in August 1979. A toxicology panel said it could not determine "a level of exposure to any of the termiticides below which there would be no biological effect under conditions of prolonged exposure."

Unable to set safety standards, the panel recommended guidelines for evacuating homes where termiticide vapors exceed certain levels.

Industry officials dispute the guidelines' validity saying that, if properly injected into the soil away from houses, termiticide vapors do not reach dangerous levels indoors.

Studies of chlordane, however, suggest that it is either more mobile than Velsicol states or commonly misapplied.

In 1982, the Air Force evacuated 200 housing units contaminated at levels exceeding the academy guideline of 5 micrograms per cubic meter of air. Beginning the next year, a New York state survey of 515 homes treated by the termiticide showed excess levels in 6.4 percent of them.

Charles H. Frommer, Velsicol's vice president for regulatory, government and public affairs, said that, even at 5 microgram levels, company studies show that chlordane poses no health problem.

"Doses people are exposed to in their homes are much lower than the maximum tolerated dose that animals have been exposed to where we've seen any kind of health effect at all," he said of the chemical. "Toxicologists tell us that, maybe if it exceeds 50, something ought to be done about it."

The New York state health department projected chlordane's cancer risk at between 1.6 and 5 additional cases of cancer among every 1,000 adults breathing 5 micrograms of the vapors over a lifetime—from 1,600 to 5,000 times higher than the federal agency's standard of acceptability.

Epstein, professor of occupational and environmental medicine at the University of Illinois Medical Center, said the New York study "grossly underestimates" chlordane's cancer risk by not considering certain cancer-causing ingredients. He estimated that exposure to 5 micrograms produces as many as two additional cases of cancer for every 100 persons.

With studies and case histories linking chlordane to a range of other diseases—including leukemia, aplastic anemia, central nervous system symptoms ranging from behavioral changes to convulsions and miscarriages—the EPA is widely criticized for lax regulation.

"If EPA doesn't have enough information to ban this chemical, then they'll never have enough information to ban a chemical," said Diane Baxter, a toxicologist at the National Coalition Against the Misuse of Pesticides. "EPA has demonstrated an extraordinary lack of will to fulfill its mandate of regulating these chemicals and protecting the public health," she said.

Carpenter, 63, retired in 1985 after 25 years as a secretary and recalls being "happy as a lark" then in what she called "my sanctuary": her three-story, four-bedroom condominium town house bought seven years earlier for $41,000.

On April 6, 1985, she noticed thousands of termites behind the living room curtains in what became a plague of biblical proportions.

Two weeks later, exterminators bored holes in the brick base fronting the house and injected chlordane, she said. They also inserted it in holes in the cement-slab foundation close to air ducts in the basement floor, she said.

Termiticides are to be injected directly underground around a house where bugs nest. They are not to be applied near people or heat or air-conditioning ducts that circulate air throughout a house.

> *"My life disintegrated .... The rage inside me won't go away."*
>
> —Christine Carpenter

A few hours after the exterminators finished, Carpenter said, she discovered white fluid covering most of the basement utility-room floor.

She threw out a soaked rug and

newspapers and mopped the floor, becoming unusually tired. For five months, her once-robust health steadily deteriorated. Small tasks exhausted her. Her spinal column became numb. Her joints hurt. She suffered headaches, nausea, depression, disorientation, memory loss, anxiety, irritability, breathing difficulty and muscle spasms.

"I thought I was falling apart from old age," she said. "The way I was feeling, I knew I was going to end up in a wheelchair, and I cried."

After watching a television report about chlordane in May, she began doing research on the termiticide. The National Capital Poison Center read her a list of symptoms linked to chlordane exposure, and "it started to strike home," she said.

An air sample of her condominium, taken in May, registered chlordane levels of 43 micrograms, more than eight times the academy guideline.

A Velsicol official assured her that there was no problem. Local and federal officials were unavailable or unresponsive, she said. Exterminators returned for a cursory cleanup. Decontamination specialists tore out part of the basement ceiling and closets without substantially decreasing chlordane levels. Another consultant offered to detoxify the house for $41,000, its original price. And, Carpenter was becoming sicker.

Finally, she abandoned her "sanctuary" in late September and rented a two-bedroom apartment off the Beltway in Annandale for $565 a month.

Faced with rent and mortgage payments and medical bills, Carpenter was forced out of retirement and works as secretary for temporary services agencies. She began regaining her health about nine months after leaving the house but still complains of lingering physical and emotional problems.

"My life disintegrated," she said. "When you lose everything you worked for, and the people who took it treat you with indifference, and you pay taxes to those glorified agencies that do nothing, you carry around a lot of bitterness. The rage inside of me won't go away."

Carpenter said she does not plan to return to her condominium. But she pays the monthly mortgage for fear that her lender will foreclose and resell the property.

"I know the agony and anguish I went through," she said. "I would never let anybody else be hurt by that house."

Even at heavy exposures, Velsicol's Frommer said, corporate health studies of chlordane show no evidence of the kind of health problems suffered by the Dines and Carpenter. "I won't argue the fact that they have symptoms," he said. "But I'd certainly argue that they got them from chlordane. The symptoms that are being alleged could come from anywhere or anything."

The burden of proving specific health problems caused by chlordane has stymied court suits for years. Ben DiMuro, a lawyer representing Carpenter and four other families alleging chlordane contamination, said Velsicol has been named in more than 150 complaints involving chlordane in the last eight years and has won all but a few cases that the firm decided to settle out of court.

Although the company has never lost a jury trial, he said, medical evidence has been strong enough in the last year that juries in Illinois and Georgia awarded large verdicts against exterminators in chlordane cases. An attorney for Velsicol refused to discuss the company's litigation.

Senator **Boschwitz**. The article notes, Mr. Chairman, that these chemicals we are talking about, cyclodienes, "are blamed for contaminating a substantial portion of the 1.5 million U.S. homes treated every year, sometimes making the risk of cancer an estimated thousands of times higher than the Federal Government considers acceptable." When you are talking about water, as you just were, these chemicals are very highly dangerous.

"Very probably, we are dealing with potent carcinogenic and toxic agents to which tens of millions of Americans are unknowingly exposed over long periods of time in the so-called safety of their homes." And Mr. Chairman, that is a direct quote by Dr. Samuel Epstein, an international authority on adverse health effects of toxic chemicals. And the article goes on to cite some specific cases.

I became interested in the issue through my acquaintance with a family that is suffering from the effects of cyclodienes. Their home was sprayed for termites with chlordane and, after 2 years of suffering illnesses that were finally traced to these chemicals, the family was forced to abandon their home, which is not an unusual occurrence with these chemicals at all. A buyer was finally found and given full warning of the problems, and the house was sold, I believe, at about $120,000 under its market value. The family suffered ailments for many, many months before it was properly diagnosed, and then had a long, uncomfortable treatment, and now must wonder what impact this has had on their life span. A friend and neighbor of my administrative assistant is terminally ill from cancer believed caused by these chemicals.

These are not isolated incidents, Mr. Chairman. That is why we must act and must act now to end the use of cyclodienes. I urge the committee to include my legislation, S. 1427, in the FIFRA reauthorization we will undertake later this year.

Mr. Chairman, I have with me Jim Aidala. He will pronounce his name. I have not had the opportunity and pleasure of meeting Mr. Aidala before this time, and he is from CRS. He also has some testimony to give.

Senator **Pryor**. Thank you, Senator Boschwitz. Mr. Aidala.

STATEMENT OF JAMES AIDALA, SPECIALIST IN ENVIRONMENTAL POLICY, CONGRESSIONAL RESEARCH SERVICE, THE LIBRARY OF CONGRESS

Mr. **Aidala**. Thank you, Mr. Chairman. I assume that my prepared statement will be entered into the record. I would just like to summarize it for now, and I would like to state that the Congressional Research Service welcomes this opportunity to be of service to the committee as it continues its work on possible amendments to FIFRA.

I have been asked to testify as to the regulatory history of certain pesticides used to control termites, as well as regulatory options EPA has under current law or other pending legislation. My remarks will center on one particular chemical used to control termites, chlordane, although generally they will apply to the entire class of related compounds known as cyclodienes.

Chlordane is a chlorinated hydrocarbon insecticide first approved for use in the United States in 1948. Over time it became one of the more widely used pesticides for both agricultural and nonagricultural applications. In 1974, as Senator Boschwitz indicated, EPA moved to end uses of chlordane since laboratory tests indicated that it caused cancer in animals, and when the risk information was extrapolated, EPA concluded that the risks outweighed the benefits and ended most uses of the pesticide in 1978.

At that time one notable exception was EPA's continued registration for use in termite control. Exposure in this case was presumed to be minimal as chlordane was thought to bind to the soil and is sealed in and around the foundation of the dwelling and other wooden parts that were to be protected.

Since 1978, EPA has continued to review the question of chlordane exposure, especially after other studies by agencies such as the General Accounting Office and the U.S. Air Force indicated that exposures may be occurring.

In 1984, EPA called for further data to make a complete assessment of the pesticide, and just now as this data is being generated by the manufacturer, EPA has reportedly calculated that chlordane exposure in properly treated homes could result in a surprisingly high risk level.

These data and associated risk levels have been widely cited in the trade press, newspapers, and other congressional hearings, such as Mr. Waxman has had before the House Energy and Commerce Committee. Specifically, it has been reported that these studies indicate an increased lifetime probability of contracting cancer of 3 in 1,000. If true, these would be extraordinarily high-risk estimates when compared to most other chemical exposures regulated by Government agencies.

As a practical matter, regulatory agencies have tended to use an elevated lifetime risk of cancer of 1 in 1 million as a benchmark to judge if further regulatory scrutiny or action is warranted.

If these new estimates cited for exposure to chlordane are, in fact, true, these would be among the highest ever encountered by EPA. EPA has authority and responsibility to review the information and take appropriate regulatory actions.

If they conclude that a currently registered product presents an unreasonable risk, they have two options. These options are called cancellation and suspension. A notice of intent to cancel initiates a process which eventually may remove the registration of the pesticide product. The key difference between cancellation and suspension is that if the EPA cancellation notice is challenged, use of the product is allowed until the proceeding is completed.

A suspension order, on the other hand, is an imminent hazard finding that immediately stops the use of the pesticide product while the cancellation process is carried out. If a pesticide is canceled following a suspension order, the registrant and others who hold existing stocks of the pesticide are subject to indemnification by EPA, according to section 15 of FIFRA. There was a long discussion this morning about indemnification by Mr. Synar and other members of the committee.

Specifically in Senate bill 1427, introduced by Mr. Boschwitz, the provisions are very straightforward. The bill would simply cancel the registration of chlordane and the other cyclodienes.

If Congress determines that there is a sufficiently high risk to public health and the environment, this unusual step of legislating about particular chemicals may be warranted. As Mr. Boschwitz indicated, this would be an unprecedented step in the history of FIFRA because Congress would then be intervening in the registration decisionmaking process. On the other hand, it was attempted in 1978 when the House passed reauthorization of FIFRA included a ban on another specific pesticide, toxaphene. In conference, the proposal was dropped by the House conferees especially since EPA had in the meantime moved to end most uses of the pesticide.

The biggest single difference between cancellation of registrations by the current provisions of FIFRA and doing so legislatively, for example through S. 1427, is simply time: cancellation hearings have taken up to 3 to 5 years, and specifically in terms of chlordane, it may take less time since there is much more of a record built about the compound.

Senator PRYOR. Pardon me. I must say that we do have a vote. The first bell rang about 6 minutes ago. I will have to leave shortly. If you could summarize in the next moment or two, I may have a couple of questions, and I do apologize for interrupting your statement.

Mr. AIDALA. No trouble. The key notion is, that at a minimum, EPA officials say that it would take at least another 18 to 24 months to complete a cancellation proceeding. Also, if you then felt that this period of time of allowing use was something you wanted to avoid, EPA could suspend the product, in which case they would then be subject to indemnification costs, which would be a minimum of $53 million, not including the costs of disposal, which are much higher.

I will stop right there and take your questions. The key point is that there are few other implementation aspects of such a provision that the committee may want to consider. In conversations with staff, I think the committee is aware of these possible issues and will take care of them during later deliberations.

[The prepared statement of Mr. Aidala follows:]

Congressional Research Service
The Library of Congress

Washington, D.C. 20540

TESTIMONY BY MR. JAMES AIDALA
SPECIALIST IN ENVIRONMENTAL POLICY
CONGRESSIONAL RESEARCH SERVICE
LIBRARY OF CONGRESS

Before the Senate Committee on
Agriculture, Nutrition, and Forestry
United States Senate
July 30, 1987

Mr. Chairman, the Congressional Research Service welcomes this opportunity to be of service to the Committee as it continues its work on possible amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). I have been an analyst specializing in FIFRA issues for over four years at CRS; before that my professional experience relating to pesticide regulatory issues includes positions at the Environmental Protection Agency (EPA) Office of Pesticides and Toxic Substances, and with the U.S. Senate staff of then Senator Charles H. Percy (Ill.). Specifically, I have been asked to testify as to the regulatory history of certain pesticides used to control termites, as well as regulatory options EPA has under current law or other pending legislation. In particular, one bill before the Committee, S. 1427 would cancel the current registrations of cyclodiene pesticides used to control termites. My remarks will center on one particular termiticide of this class, chlordane, although generally they will apply to this entire class of related compounds.

BACKGROUND

Chlordane is a chlorinated hydrocarbon insecticide first approved for use in the United States in 1948. Over time it became one of the most widely used pesticides for both agricultural and non-agricultural applications. Questions about its potential for causing widespread environmental harm became especially controversial in the late 1960s.

Chlordane is a persistent compound which degrades very slowly in the environment. It has been found to persist in the soil for decades, and is insoluble in water--it becomes tightly bound to soil particles. It accumulates in the fatty tissues of animals which ingest the compound, and as a result, concentrations of these residues can become magnified as they are passed up the food chain. Residues have been reported in many living organisms, including humans. Chlordane and its degradation products have been found in rivers, lakes, streams, and in some cases, public drinking water supplies. Similarly, residues have been found in meat, fish, dairy products, poultry, and eggs.

In 1971, the newly created Environmental Protection Agency (EPA) initiated a formal review of the risks and benefits of chlordane and the other cyclodienes. Authority to regulate pesticide use is given to EPA through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA controls pesticide use through a licensing process called "registration": a product cannot be used in the United States without an EPA-approved registration of the intended application. To receive a registration, the applicant must convince EPA that the product is safe; that is, it will not cause unreasonable adverse effects to humans or the environment.

Once a registration is granted, and new evidence is gathered which shows that the approved pesticide may be causing an unreasonable risk (that is, that its risks outweigh its benefits), EPA can initiate certain reviews which can eventually result in the revocation of the registration. EPA began such proceedings on chlordane in 1974. Laboratory tests indicated that chlordane caused cancer in animals, and when the risk information was extrapolated, EPA concluded that the risks of chlordane outweighed its benefits in almost all uses; most uses of the pesticide were cancelled in 1978. During its review of the pesticide, EPA estimated that almost every person in America had residues of chlordane in their body tissues. It was presumed that the source of virtually all of the chlordane in the environment was due to the previously registered agricultural and home garden uses. Since EPA banned most uses of the pesticide, levels of chlordane in human tissue have decreased, but have not been eliminated.

One notable exception to EPA's cancellation of chlordane registrations was its use for termite control; in recent years its continued use has become increasingly more controversial. In 1975, there were no other pesticide certified as an effective and safe substitute available for chemical control of termites, although some compounds appeared promising. In 1978, EPA determined that continued use of chlordane (and the other cyclodienes) as a termiticide would not present an unreasonable risk, because when properly applied, it was assumed that little or no chlordane would enter the environment. As a result, EPA concluded at the time that the continued benefits (as the only certifiably effective termiticide) outweighed estimated risks (estimated to be low if human and environmental exposure were minimal).

If applied properly, chlordane is injected into the soil around the foundation of a building when it is built, or through holes drilled into the foundation after the building is constructed. Exposure to humans and the environment was presumed to be minimal as the chlordane binds to the soil and is sealed in and around the foundation. However, questions about the potential for unintended exposures, through misuse (e.g., drilling holes into air heating ducts) or unforeseen events (e.g., cracks in the foundation), led to calls for a re-examination of the situation and further restrictions on the use and sale of the pesticide.

In November 1983, EPA completed a new analysis of the risks and benefits of various termiticides, including chlordane. Once again it was concluded that the benefits of continued use of chlordane (and related compounds) outweighed the known risks. At the same time, EPA acknowledged that the data necessary for a definitive risk assessment of these compounds were unavailable at that time.

Following its 1983 review, in 1984 EPA issued certain data requirements in order to more definitively assess the risks and benefits of chlordane. Late in 1986, EPA issued its Registration Standard for chlordane (a Registration Standard is a review of existing data about a pesticide conducted by EPA to determine whether additional data are necessary to reregister the pesticide), which proposed to restrict its use to certified applicators (a certified applicator is one who has been instructed in the proper use of pesticides through participation in EPA-approved State programs) and called for further data to make a complete assessment of the pesticide.

Meanwhile, certain States, particularly Massachusetts and New York, initiated independent reviews of termiticides and no longer allow use of chlordane. Recently, Minnesota has stopped the use of chlordane, and officials in Rhode Island are in the middle of a decision-making process which may end the use of chlordane in that State. Maine technically allows the use of chlordane by permit only, but reportedly no permits have been issued in the past few years.

However, in early 1987, based on studies requested by EPA and conducted by the registrant (Velsicol Corporation), some EPA reviewers claimed that new air monitoring studies indicated that chlordane exposure in properly treated homes could result in a surprisingly high risk level. This report and its associated risk levels have been widely cited in the trade press, newspapers, and other Congressional hearings. Specifically, it has been reported that these studies indicate an increased lifetime probability of contracting cancer of 3 in one thousand. If true, these would be extraordinarily high risk estimates when compared to most other chemical exposures regulated by government agencies. As a practical matter, regulatory agencies have tended to use an elevated lifetime risk of cancer of one in one million as a benchmark to judge if further regulatory scrutiny or action is warranted. If the new estimates cited for exposure to chlordane are true, this would represent a level 3,000 times the "benchmark" level. Put more simply, these levels of estimated risk would be among the highest ever encountered by EPA. What makes the situation different from past cases, such as the controversies surrounding ethylene dibromide (EDB) in 1983-84, is that the chlordane risk estimates would appear to be based on actual exposures. Such estimates should be more precise than the more common reliance on assumptions or extrapolations about the maximum amount of residues on treated fruit, extrapolated amount of fruit a person eats, and so on, because it reportedly is based on monitoring data from treated homes. It should be noted that any risk assessment includes a great many assumptions and extrapolations, even if some actual exposure data is included, and legitimate disagreements may be raised by others who review this same information.

EPA has the authority and responsibility to review this information and take appropriate regulatory actions about this, or any other, pesticide. According to the present provisions of FIFRA, they have two main regulatory options if they conclude that a currently registered pesticide presents an unreasonable risk.

REGULATORY OPTIONS FOR ENDING A REGISTRATION: CANCELLATION AND SUSPENSION

EPA can revoke a pesticide registration if information indicates that it presents an unreasonable risk of adverse effects on human health or the environment. This process of "de-registration" is an elaborate one, and is known as cancellation or suspension of the registration.

A notice of intent to cancel initiates a process which eventually "cancels" the registration of a pesticide product. The EPA proposal to cancel can be challenged by the registrant and other affected groups. If the EPA notice is challenged, use of the product is allowed until the cancellation proceeding is completed. If EPA "suspends" the registration, use of the product is forbidden while the cancellation process is conducted. In effect, a suspension order is an imminent hazard allegation that immediately stops the use of a pesticide product, while the cancellation process is carried out.

A suspension order immediately stops the sale and use of a pesticide, and initiates the cancellation process. However, if a pesticide is cancelled following a suspension order, the registrant and others who hold existing stocks of the pesticide are subject to indemnification by EPA according to Section 15 of FIFRA. Furthermore, current budget policies require that any monies for indemnification are to come from the operating budget of EPA's pesticide program, whose current annual budget is approximately $70 million.

Indemnification can be expensive; EPA estimates that the most recent suspension order for the herbicide dinoseb may require indemnification costs as high as $60-125 million.

The cancellation proceeding is not unlike a formal courtroom trial of the pesticide registration. An Administrative Law Judge presides over an adjudicatory hearing process which allows evidence to be introduced and witnesses to testify and be cross-examined. The Administrative Law Judge is not necessarily familiar with FIFRA or with the kinds of regulatory issues involved with regulating pesticides (such as toxicological testing or agricultural practices). Both sides in the dispute create an entirely new record--the work of EPA or the challengers has to be introduced as if no decision had been made at all up to that point, and the record developed in the hearing is the only evidence the Administrative Law Judge considers in making a decision. The Administrative Law Judge makes a recommendation to the EPA Administrator. The Administrator's final decision point can be challenged in a U.S. Court of Appeals. The record reviewed by the court is the hearing record developed before the Administrative Law Judge.

This cancellation and suspension process was contained in the 1947 FIFRA. From 1947 to 1970 only one suspension or cancellation order was issued under FIFRA, and it was overturned by the court. [1] Procedural safeguards which are part of the cancellation hearing process help guarantee that the government can not arbitrarily revoke a registration without cause. The rationale for cancellation has to be laid out in the decision-making record developed before the Administrative Law Judge.

When EPA was created in 1970, the provisions of the 1947 FIFRA were in force, and the Agency attempted to control the use of certain pesticides through cancellation hearings. These hearings became long, complex, and controversial proceedings which lasted 3-5 years and left many observers critical of this approach to pesticide use control. In response to these criticisms, in 1975 EPA initiated what is now called the Special Review process as an attempt to substitute for the complex and resource-intensive cancellation hearing process.

Originally designed to be an eighteen-month exercise, what is now called a Special Review was to be an intense examination of a product's risks and benefits, done in a shorter, more informal, and less resource-intensive way than formal adjudicatory hearings. A product came under an RPAR review if it met or exceeded one or more of certain "triggers" -- hazard criteria that identified pesticides deserving priority review. Triggers included evidence of carcinogenicity in laboratory animals, or extreme toxicity to other non-target animals such as fish or birds when used to control pests. This information could be discovered as part of a reexamination of data already submitted to EPA, or might be new data brought to the attention of EPA, such as data developed by the registrant, academic researchers, or other Federal agencies. Special Reviews can take years to complete; for example, EDB was in Special Review for approximately seven years. Even a relatively non-controversial or straightforward Special Review would take a minimum of nine months.

When the conclusion of the Special Review is an EPA decision to cancel certain uses, the registrants or other affected parties retain their rights to a hearing according to the provisions of FIFRA.

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[1] While FIFRA was administered by the U.S. Department of Agriculture, only one suspension order was issued. It came after children were poisoned by eating pork from hogs which had been fed mercury-treated seed grain. The grain was mistakenly fed to the hogs, and the children were made ill by eating the pork with accumulated mercury in the meat. The order was overturned because it could not be determined that the illness was due to the mercury treatment; rather, the problem was the mistaken feeding of the hogs.

S. 1427

The provisions of S. 1427 are straightforward; the bill would cancel the registration of chlordane and the other cyclodienes (heptachlor, aldrin, and dieldrin). It would also forbid the Administrator from reregistering any of these pesticides.

If Congress determines that there is a sufficiently high risk to public health and the environment, this unusual step of legislating about particular chemicals may be warranted. However, this would be an unprecedented step in the history of FIFRA, and may set a precedent of Congress intervening in the registration decision-making process. One previous attempt to legislatively end the use of a specific pesticide came in 1978, as the House-passed reauthorization of FIFRA included a ban on the pesticide toxaphene (a compound chemically similar to chlordane). In conference, the proposal was dropped by House conferees, especially as EPA had in the meantime moved to end most uses of the pesticide. Nonetheless, Congress has required specific regulatory outcomes about chemicals in other statutes (for example, the Toxic Substances Control Act (TSCA) of 1976 banned the further manufacture and general use of polychlorinated biphenyls (PCB)).

The most significant difference between cancellation of registrations by EPA and doing so legislatively is time: cancellation hearings have taken 3-5 years on average, cancellation by including such specific language in the statute, unless otherwise provided for, would become effective immediately upon the effective date of the statute. If cancellation hearings follow a Special Review, the entire process can take up to 7-10 years. Chlordane, given the amount of regulatory attention it has already received, should take far less time for EPA to consider. However, EPA officials have estimated that any cancellation proceeding, with or without an "expedited" Special Review, would probably not be completed for 18-24 months. Furthermore, if existing stocks of the pesticide were allowed to be used, then chlordane could conceivably be used for many months beyond this period.

Current estimates by EPA and the pesticide-treatment industry estimate that approximately 1.2-1.5 million homes are treated for termites annually. The market share of chlordane-treated homes has also declined over the last seven years, according to industry and EPA estimates, and now stands at approximately 50-60%. An estimated 40-50 million homes have already been treated with cyclodiene pesticides. Use of chlordane is expected to decline further; for example, in a letter dated July 21, 1987, officials of the Orkin Pest Control Company have informed EPA that the company expects to end the use of chlordane within 60 days. As a result, it is unclear how many more dwellings might be treated with chlordane while EPA completes its review.

If EPA were convinced that an imminent hazard existed and immediate action was warranted, they have authority to suspend the pesticide's registration. However, if the suspension was eventually followed by a cancellation of the registration, EPA would have to indemnify owners of existing stocks of the pesticide. For chlordane, EPA has estimated that the cost of indemnification for chlordane would be $53 million, not including the costs of disposal. Disposal costs for chlordane can be expected to be high, given the stability of the compound and the fact that incineration is the most likely disposal option. As a result, disposal costs could be some multiple of the purchase price.

One other issue has been raised about the implications of cancelling a registration statutorily. Under current practice, if EPA cancels a pesticide, or suspends a product followed by a cancellation order, directives concerning the status of existing stocks are included. This may include a phase-out of existing stocks, a date after which no more of the pesticide may be sold or used, or an order for an immediate end of use and instructions about indemnification procedures to be followed, among other things. Legislative cancellation is a new area which may leave the status of existing stocks and other supplies in the channels of trade uncertain.

If and when S. 1427 is considered by the Committee or the full Senate, proponents of an immediate cancellation through the statute may wish to include specific directions for EPA and the affected user community concerning the handling, storage, transportation, and disposal of existing stocks of these pesticides.

Senator **PRYOR**. I want to thank you on behalf of the committee for your very splendid testimony. My first question: Why does it take so long to make regulatory decisions on these pesticides that are being studied and are being subjected to, evidently, a higher degree of risk, or allegedly create a higher degree of risk? Why does it take so long?

Mr. **AIDALA**. Two reasons. One, they are inherently very complex issues, especially when you are considering a currently registered product. That means that it is in use and EPA at one point said it was safe to use. This means that new evidence has been gathered or other evidence has somehow come about. And then specifically within FIFRA, the cancellation proceeding is an adjudicative hearing before an administrative law judge, and you have to have full entering into the record of all the information you want to put in. There is also cross-examination of witnesses. The point is there is lots of procedural steps and things that take place that do tend to drag out the proceeding.

Senator **PRYOR**. Now should we speed that process up?

Mr. **AIDALA**. That is, of course, up to you. The current provisions in the bill before the committee in S. 1516 would help that process in some cases for compounds that already go through some regulatory review called Special Review at EPA.

I think that things like Senate bill 1427 indicate that some members feel that it ought to be speeded up.

Senator **PRYOR**. All right. Now I remember some years ago, perhaps 10 or 12, that EPA took cranberries off the market. What was it that we took off? Was it cranberries?

Mr. **AIDALA**. The cranberry scare was back in the late 1950's. I don't know if you are showing your age or not.

Senator **PRYOR**. Late 1950's. Time goes very quickly.

Mr. **AIDALA**. Although there are many other cases along the way. Most recently EDB was an example where we had a lot of concern about treated grains and wheat and baked goods and things of that sort. This does periodically happen.

Senator **PRYOR**. Now there is a way that we could sometimes move too quickly, I guess, on taking products off the market, or certain pesticides off the market. Then we look back and say, wait a minute, we made a mistake there. Is that correct? So we are trying to achieve a balance.

Mr. **AIDALA**. Exactly; and FIFRA is a balancing statute and part of the reason for what might be seen by some as onerous procedural hoops to go through is to guarantee a full hearing of the evidence.

Senator **PRYOR**. All right. In your opinion, does S. 1516 achieve that balance?

Mr. **AIDALA**. It seeks to continue and further refine the proceedings. Again, in one kind of proceeding called Special Review, that body of evidence would be automatically entered into the record. Hopefully that will speed up the cancellation process in those cases.

Senator **PRYOR**. All right. So the record will reflect this. It is my understanding of Senator Boschwitz' proposal that it would just automatically take this product off of the market or remove its registration; is that the case?

Mr. AIDALA. Assuming that it is also fixed to deal with disposal of existing stocks and products that are in the channels of trade. The key point is it would be Congress making that decision, that given the evidence at this point, Congress is saying this is the decision about that registration.

Senator PRYOR. Senator Boschwitz.

Senator BOSCHWITZ. I just want to say that you mentioned the figure that normally the EPA acts in the event that there is a one chance in a million, and in this case there are 3 chances per 3,000.

Mr. AIDALA. 1,000.

Senator BOSCHWITZ. Three chances per 1,000, Mr. Chairman, as opposed to 1 chance per million.

Senator PRYOR. In 1 million. I want to thank both of you and I want to apologize for having to leave. If our next panel would stay seated, and the other two panelists or witnesses come forward, either Senator Harkin, myself, or some other Member of the U.S. Senate will come up here and receive your testimony. We will have a short recess.

[Recess.]

Senator LUGAR [presiding]. The hearing is called to order again, and I call for the panel of public interest witnesses. I am pleased to recognize each one of you. We thank you for your enormous patience in waiting till this point in the program. As the presiding officers have pointed out before, all of your statements will be made a part of the record, and I would like to proceed, hopefully with the customary 5 minute limit as much as it is possible.

I would like to recognize first of all Mr. Rick Hind, the environmental lobbyist of U.S. Public Interest Research Group of Washington, DC.

STATEMENT OF RICK HIND, ENVIRONMENTAL LOBBYIST, U.S. PUBLIC INTEREST RESEARCH GROUP, WASHINGTON, DC

Mr. HIND. Thank you, Senator. We appreciate the opportunity to testify here today with other environmental, labor, and consumer organizations. U.S. Public Interest Research Group is the national lobbying office for State Public Interest Research Groups [PIRG's] across the country.

We have put FIFRA as one of our highest legislative priorities in Congress this year.

We want to applaud you, Senator Lugar and Chairman Leahy, for your wisdom in excluding any form of preemption in the bill that you have introduced, S. 1516, as well as any exemptions for liability. We think that is a substantial improvement over the House bill, much of which you have borrowed in incorporating your bill this year. We view the preemption and liability provisions that were in the House bill as bill killers.

The preemption, in our view, is one of the things that helped to kill the legislation in 1986, and we think it is unacceptable as part of any FIFRA legislation this year or any other year.

We also agree that limiting indemnification and increasing fees is an important step, and of course, the new registration program is an improvement in current law. However, as Mr. Nader called it this morning, FIFRA is a no-law law. We think the urgency of the problem with pesticides merits much more. We think the law is very skewed in actually promoting pesticide use, and not controlling exposure to what I have called the handgun of toxic chemicals, chemicals that are only made for one purpose, and that is to kill.

We are not for banning all synthetic chemicals. Only 1 percent have been found to be very dangerous, but pesticides are, I think, a special class in that regard.

In the area of indemnification, we were glad to hear EPA's John Moore this morning call for a total repeal of that provision. We think that if we do not support a public policy of insuring industries for the production of dangerous chemicals, we should not have it even as line item possibility in future appropriations. We also think that the bill should go further by not allowing the Agency to bear the burden of disposal costs but rather to have the chemical producers assume all costs of disposal, and have EPA supervise the disposal and safe storage in the meantime, possibly using the Solid Waste Disposal Act requirements and perhaps new ones specifically designed for pesticides.

On fees, your bill is better than either bill last year, in providing more money for registration. However, the Agency has now estimated a greater need in reregistration programs. We are fearful that the $110 million in appropriations share of the money for the reregistration may not be entirely reliable in future years with Gramm-Rudman and all. And the $37 million shortfall in S. 1516 fees concerns us that again the reregistration program of 9 years, may be in jeopardy.

We support greater fees or authority to the Agency to levy fees should there be a shortfall which could endanger the reregistration schedule. On exports, we need to go beyond last year and ban all chemicals which are banned or restricted here in the United States, so that we do not sell them overseas to be used on the food we import. We shall also require that the export of any pesticides from this country go only to countries with equivalent regulatory systems to the United States. We are also dealing with a human rights issue by sending chemicals to other countries. In the case of Bhopal, India, Indians at the Union Carbide factory were led to believe that a warning of MIC leak would just be a watering of the eyes. They did not know that the time between that and their death would be almost negligible.

In terms of the reregistration program, we still need to close the loopholes that allow and promote the continued use of not fully tested chemicals in the minor use, conditional registrations, and special local needs exemptions. Also drift control is not addressed even though all of the contamination that we face, whether it be food residues, or ground water contamination, is proof of the failure of pesticides to hit only their target. In fact, they go off target, as many applicators have admitted, hitting neighboring schools, reservoirs, and hospitals instead of the target areas, and threatening other crops and livestock.

On ground water we certainly recognize that S. 1419, introduced by Senator Leahy and Senator Durenberger is a positive improvement over either ground water provision in last year's ground water sections of FIFRA legislation.

However, the MCL waiver requested by EPA in the MCLG health based standard in S. 1419 worries us because, as was earlier demonstrated in the dialog between NACA witnesses and Senator Harkin, we see an easy misconstruing of this language, and the waiver could end up being the tail that wags the dog. And EPA is doing just that with an even narrower waiver in the current Superfund cleanup standards, which the Members of Congress from both parties who wrote that legislation have protested vigorously.

On right-to-know, again with pesticides, we are treating the American public as guinea pigs, and the American public is being asked not to know what is in products, or what should be on the label. The inert ingredients are trade secrets. And in the case of local communities, especially in rural America, the Superfund right-to-know program leaves an information gap for rural Americans.

The April 4 Minot, ND accident fire at a pesticide warehouse containing 54 pesticides, well over 100,000 pounds stored, left that community with 10,000 people evacuated for 2 days. People did not know what was in the warehouse until after the fire. We were told by EPA to put in a Freedom of Information request in order to get full information about the pesticides there.

On citizen suits——

Senator LUGAR. Are you close to the end?

Mr. HIND. I will sum up.

Senator LUGAR. In fairness to the others, I think probably we need to finish.

Mr. HIND. In regard to citizen suits, FIFRA is the only major environmental law that does not have such a provision. We think FIFRA needs a provision similar to section 505 of the Clean Water Act.

On patent term, we think, as Mr. Nader pointed out, we need to have more facts to justify it before we provide such a giveaway to the industry.

In the matter of worker safety, the people who harvest our food deserve not a double standard, but a high standard of protection, and also should receive protection through recordkeeping, another essential element of right-to-know.

I think these are all reasonable requests. They are all within the scope of last year's legislation. I think people will eventually say that we did not do enough even if you do everything that we have suggested. But we look forward to working with you in achieving these goals. Thank you.

Senator LUGAR. Thank you very much.

[The prepared statement of Mr. Hind follows:]

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TESTIMONY OF RICK HIND

OF THE

U.S. PUBLIC INTEREST RESEARCH GROUP

BEFORE THE COMMITTEE ON

AGRICULTURE, NUTRITION AND FORESTRY

UNITED STATES SENATE

JULY 30, 1987

U.S. PIRG 215 Pennsylvania Avenue, S.E. Washington, D.C. 20003 (202) 546-9707

Mr. Chairman, my name is Rick Hind. I am an environmental lobbyist for the U.S. Public Interest Research Group (U.S. PIRG). I appreciate the opportunity to testify today along with other environmental, consumer and labor groups. U.S. PIRG is the national lobbying office for state PIRGs across the country. PIRGs are non-partisan research and advocacy organizations that focus on environmental and consumer issues. Amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to be more compatible with other recently reauthorized environmental statutes such as the Safe Drinking Water Act, Clean Water Act and Superfund is one of our organization's highest legislative priorities in the 100th Congress.

Last year a compromise FIFRA bill negotiated between industry and environmental, consumer and labor groups came very close to enactment until it was fatally crippled by special interest amendments attached to the October 16, 1986 House passed bill (H.R. 2482) on behalf of the business community. This was unfortunate because, even though the "core" FIFRA agreement was not a complete solution, it was a net improvement over current law. The crippling amendments included the preemption of states' authority to set more stringent health standards for pesticide residues in food and a liability exemption for large pesticide users that could allow them to escape clean-up costs under all other federal environmental laws. These amendments were rejected by the Senate last year and are unacceptable as part of any FIFRA reauthorization this year as well.

We applaud the exclusion of preemption and liability exemption in the bill (S.1516) introduced last week by Senators Leahy and Lugar. We urge you to stand by your opposition to these and other weakening amendments through the final passage of a FIFRA conference report. For example, we understand that some segments of the chemical industry may propose another unacceptable form of preemption to prevent states from registering pesticides. There may also be a revivial of last year's Senate floor amendment to prevent the use of the National Environmental Policy Act (NEPA) to require Environmental Impact Statements for pesticide applications on federal lands. The Senate wisely rejected such an amendment last year.

THE PROBLEM

In 1962 Rachel Carson inspired a generation of Americans to a new level of environmental awareness. Despite the enactment of a wide range of laws to protect the environment and public health, virtually every American still risks the effects of exposure to some of the 2.6 billion pounds of pesticides used every year. For most of us, these chemicals come to us in the form of residues on our food or contaminants in our drinking water. However, millions of others are also exposed to dangerous pesticides in the air within their homes and where they work.

For example, approximately one third of all fruits and vegetables grown in the U.S. are treated with a group of fungicides known as EBDCs. Through food processing or cooking EBDCs break down into a known carcinogen, ETU (ethylenethiourea). The Environmental Protection Agency (EPA) says that the "entire U.S. population is potentially subject to dietary exposure to ETU." EBDCs are only six chemicals of 700 active ingredients that are part of 60,000 pesticide products.

Of the 700 active pesticide ingredients, 496 may be found in our food supply. On May 20th the National Academy of Sciences reported that 90 percent of all fungicides, 60 percent of all herbicides and 30 percent of all insecticides may cause cancer. Yet the EPA can only cite three instances when they denied the use of a pesticide because of the supposedly restrictive Delaney Clause in section 409 of the Federal Food, Drug and Cosmetic Act (FDCA). The Delaney Clause prohibits the approval of food additives that "induce cancer." This is a very important public health requirement because little is known about what constitutes "safe levels" of human exposure to a carcinogen, especially to sensitive subpopulations such as pregnant women and children.

Last year, the General Accounting Office (GAO) released two studies (in September and October) that documented how the Food and Drug Administration (FDA) is not adequately monitoring or enforcing the FDCA to protect the nation's food supply. The October study (entitled: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues) revealed that the FDA's multi-residue tests were able to detect only 41 percent of pesticide residues that might appear in food. And while 25 percent of our fresh fruit comes from abroad, the September GAO report (entitled: Better Sampling and Enforcement Needed on Imported Food) found that the FDA is monitoring less than 1 percent of imported foods.

The need for strong legislation is self evident. EDB is still showing up in the Connecticut River 16 years after its last use; DBCP is increasing in the groundwater in Fresno County, California eight years after it was banned; the National Cancer Institute found that farmers exposed to herbicides, just 20 days a year, had a sixfold increase in cancers; and toddlers today are eating fruit and baby-food and drinking juices known to contain residues of dangerous pesticides.

PREEMPTION OF FOOD SAFETY STANDARDS

The preemption proposal made last year, which is likely to be offered again this year, to strip the authority of states to set more stringent food residue standards for pesticides represents a callous disregard for public health. Again Mr. Chairman, we applaud you and Senator Lugar for excluding such a provision in S.1516. The only appropriate role the federal government has in preempting states' authority is in setting minimum health protection standards, not the maximum standards set in last year's House bill. According to the National Governors Association, "as long as states have confidence in federal standards, there will be little, if any, incentive for them to adopt more stringent requirments. But when the federal government strikes a balance between risks and benefits, which the state considers inappropriate, the state has an obligation to enact its own tougher standards."

The federal government's track record on pesticide residues in food far from merits giving either the EPA or the FDA the last word in determining food safety in this country. For example, it was states such as Florida who acted first to begin limiting EDB. EDB remained on the market and in our food while EPA had it under special review from 1977 until it was suspended in 1984. Today daminozide is another example where states such as Massachusetts and New York are moving ahead while the federal government lags behind. While some states have taken decisive action when a threat was at hand, there certainly has not been a pattern of abuse or frivolous claims by any state.

Preemption could also result in reduced monitoring by states of their intra-state food products, relying instead on the federal government's monitoring of its standard and thus increasing the FDA's monitoring burdens. And although the implementation of preemption by the federal government might be optional, it is more likely that the preemption of all states would be the norm, to avoid the political problem of explaining why one state deserved greater protection than another.

Preemption would also set a dangerous precedent in modern environmental protection legislation. Major environmental statutes such as the Clean Water Act, the Safe Drinking Water Act, the Solid Waste Disposal Act and Superfund all set safety standards that states can strengthen if they choose. Should Congress allow such a provision in any form it will invite similar demands by interest groups in the reauthorization of these environmental statutes as well.

Preemption efforts in Congress on behalf of special interest groups such as the Grocery Manufacturers Association (GMA) eventually helped to kill FIFRA legislation last year. Similar efforts this year could have the same results. While the GMA tends to be invisible, its member companies, such as the H.J Heinz food company are not. Last November Heinz gained publicity, and a likely boost in sales, when The Wall Street Journal reported on Heinz's plans to phase out the purchase of crops for its baby-food line that are treated with pesticides under "special reveiw" at the EPA. (The EPA only has about 22 out of 496 food use pesticides under review.) Yet Heinz, despite its apparent sensitivity to the problem, continues to support GMA's efforts in Congress to keep states from setting more stringent pesticide residue limits in food.

LIABILITY EXEMPTIONS

Another special interest proposal offered last year that helped contribute to FIFRA's demise has also returned in the 100th Congress. The highly controversial liability exemption for agricultural producers, which was part of the 1986 House bill, is nothing more than a bail-out for giant agribusiness operations. Again Mr. Chairman, we compliment you and Senator Lugar on your wisdom in excluding such a provision from S.1516.

While such an exemption pretends to protect the small family farmer for simply using a pesticide according to the manufacturer's label, in reality such protection is redundant. Perhaps that is why the American Farm Bureau Federation this year has withdrawn its support for this exemption. In the case of a Superfund clean-up, the EPA or a state agency is looking for a "deep pocket" defendant. The small family farmer is not likely to be sought after by EPA for a typical $12 million Superfund groundwater clean-up if only because the Agency knows the farmer does not have the resources to pay for it.

Such a provision would also serve as a disincentive to the careful use of pesticides by large agricultural producers who would be more cautious if they knew they would continue to be held liable for the full cost of clean-ups. Under current law some will take greater care than the label requires because they may have to assume that liabililty. Most farmers also know they are liable under state tort laws for personal injury to employees and neighboring farmers.

Many farmers already know that these chemicals will contaminate the environment even if they are used "properly," as evidenced by the finding of 23 pesticides in groundwater of 24 states. A public opinion poll done last fall for the Iowa Department of Natural Resources found that 63 percent of Iowans surveyed believe agricultural chemicals are the main source of ground water contamination in Iowa. EPA Assistant Administrator for Pesticides and Toxic Substances, John A. Moore, testified in April that EPA knows of at least 40 to 50 pesticides that leach into groundwater. In California alone, pesticide contamination has been found in the groundwater of 28 counties.

Amendments last year to allow a liability exemption would also set an outrageous precedent for environmental laws. In one stroke it would weaken four major federal statutes. Those laws in turn would face a line-up of special interests at the next reauthorization asking for "me too" liability exemptions. No sound public health law can contain such a provison.

INDEMNIFICATION

Another serious flaw in last year's bills was the failure to repeal the current law's indemnification and amend the disposal requirements (sections 15 and 19). Unfortunately, S.1516 only keeps indemnification bail-outs from coming out of the EPA budget. It preserves section 15 for those able to successfully lobby for appropriations that the taxpayer should never have to tolerate in the first place. If the policy of indemnification is truely unacceptable, then section 15 of FIFRA should be repealed. With regard to disposal, S.1516 is silent. Here again the cost should be borne by the pesticide producer with strict requirements over the means of disoposal. In no other federal law are the costs of enforcing a regulation to protect the environment or public health placed on the regulating agency. In his testimony this April, John A. Moore called indemnification "a ludicrous statutory mandate for this Agency to fund what is essentially an insurance program for registrants."

In response to questions from Senator Proxmire, Chairman of the Senate Appropriations Subcommittee on HUD-Independent Agencies, EPA recently gave some examples of the kind of indemnification costs it could face in the near future: alachlor, $161,500,000; linuron, $35,600,000; benomyl, $78,000,000; daminozide, $7,950,000; methyl bromide, $23,000,000; chlordane, $53,200,000 and dinoseb, $30 to $50,000,000. In the past, the EPA has paid $18,000,000 for 2,4,5-T Silvex and $2,400,000 for EDB indemnity claims. Disposal costs of equal magnitude may also be incurred in the future.

What is so special about the pesticide producers that they deserve such a payoff? We do not pay automobile manufacturers or drug producers for the cost of a recall. FIFRA's indemnification provision in section 15 and related disposal requirements in section 19 should be repealed. Until we do so, the Agency may continue to balk at protecting the public health by delaying suspensions to avoid washing out its modest $60 million annual pesticide program budget. The Agency may also decide, as is rumored with the pending chlordane decision, to cancel the product but allow the use of existing inventories to reduce its disposal costs (as they did with toxaphene in 1982, see Federal Register, Vol.47 No.229 p.53785).

Producers with products under special review also have no incentive to stop making a product until a final cancellation or suspension decision takes affect. While the public is told that incorporating a zero health risk policy in FIFRA would not be "practical," what justification is there for the zero financial risk policy already in FIFRA through indemnification and disposal?

EXPORTS AND IMPORTS

Related to indemnification is the question of allowing suspended, cancelled and restricted products to be exported overseas where they are applied without our knowledge to food crops and imported back to us in the form of dangerous food residues. According to the September 1986 GAO report, Better Sampling and Enforcement Needed on Imported Food, the FDA is monitoring less than one percent of the one million food shipments that enter the U.S. every year. It is therefore naive to believe that simply requiring "prior informed consent" from a receiving country is sufficient to protect the American consumer from illegal and hazardous imported food with pesticide residues. S.1516 does not address this problem because it allows the continued export of dangerous pesticides and fails to establish a comprehensive monitoring and enforcement system to protect our markets from contaminated imported food.

The export of suspended, cancelled and restricted pesticides should be prohibited. The export of other pesticides should also be strictly regulated to ensure that they are only allowed to go to countries with regulatory programs equivalent or superior to the U.S. Coordinated with prohibition and regulation we need to mandate a comprehensive monitoring and seizure program with the resoures to identify contaminated shipments and prevent them from entering U.S. markets.

GROUNDWATER

EPA has found at least 23 pesticides in the groundwater of 24 states. Pesticides were reported in one quarter of 45,000 samples taken, and about 5,000 of these samples exceeded health guidance levels. Half of the population of the U.S. (90 percent of the rural population) rely on groundwater for their drinking water supplies. The poll done for the Iowa Department of Natural Resources also found that 84 percent of Iowans surveyed desired more stringent regulation of the use of pesticides. Iowa, Nebraska and other farm states have also recently enacted new groundwater protection laws.

Although last year's Senate bill contained a groundwater provision, it failed to establish groundwater guidance levels (GRGLs) using fully health-based standards, maximum contaminant level goals or MCLGs. In effect it was a step back from the 1986 Safe Drinking Water Act and Superfund amendments.

This year a groundwater bill (S.1419) sponsored by Senators Leahy and Durenberger was introduced in the Senate. As you consider amendments to S.1516 in Committee and on the floor we recommend that you adopt a groundwater provision at least as protective as the Leahy-Durenberger bill but preferrably stronger. At the request of the EPA, a waivor was included in S.1419's health-based GRGLs which allows the EPA to use maximum contaminant levels (MCLs) instead of MCLGs in the case of carcinogenic pesticides. EPA establishes MCLs through a risk benefit process that is highly controversial and would be codified by the "negligible risk" language in S.1419. The effect of this language is to say that there is an acceptable rate level of cancer. Given EPA's track record in abusing similar waivors under the new 1986 Superfund, we remain unconvinced that this waivor in S.1419 will result in sound health protection policy. Any widening of this waivor in Committee or on the floor would result in widespread opposition by environmental groups.

When John Moore testified before the Senate Agriculture Committee in April, he emphasized the need for "prevention." Cleaning up groundwater contamination is extremely expensive, and the longer we wait to halt the contamination, the more expensive it will become. The problem is also a long-term one. When Senator Durenberger testified before the Senate Agriculture Committee this year, he noted that much of today's groundwater supply probably fell as rain during the American revolution. Applying pesticides today with chemical half-lives of over 100 years does not bode well for the drinking water of our grandchildren.

REREGISTRATION

Since the 1972 reauthorization of FIFRA, the EPA has managed to fully reregister only 2 (metolachlor and fosetyl aluminum) of the 700 active ingredients found in pesticides. This failure, coupled with the inability to expeditiously cancel pesticides known to be dangerous (such as EDB), indicates a breakdown in public health protection of staggering proportions. The American people have become guinea pigs for the chemical industry while the government regulators and Congress debate the merits of restricting these chemical toxins.

It is crucial that the Agency be put on a reregistration schedule, and that they be given added authority to streamline FIFRA's cumbersome cancellation procedures. However, S.1516 fails to fully control the abuses of conditional registrations (half of all new pesticides have been conditionally registered), minor uses (which include such "minor" crops as brussels sprouts and egg plant) and special local needs or SLNs (SLNs granted for 61 pesticides including paraquat in 5 or more states).

The major problem of off target "drift" is also not fully addressed, leaving neighboring schools, hospitals and reservoirs at risk. And, although citizens would be allowed to participate in a cancellation hearing, the burden of going forward would be shifted from the registrant to the citizen. The bill also merely codifies the meager efforts of the EPA on inert pesticide ingredients. Many of these ingredients are as dangerous or more dangerous than some active ingredients and they should be subject to the same regulatory standards and disclosure requirements as active ingredients. These flaws are among the many in need of correction in S.1516 and the so-called pesticide control law we call FIFRA.

FEES

The fees in S.1516 also fall short by $4 million a year in producing the funds the EPA says it will need to meet its new reregistration schedule. The Agency's reregistration cost estimates have increased by $40 million since last year because the actual number of active ingredients has increased from 600 to 700 chemicals. The Agency's reregistration program needs will come to $260 million over nine years, with $110 million derived through appropriations and $150 million to be raised in fees. The fees in S.1516 will raise $113 million, leaving a shortage of $37 million over nine years. This bunding gap could be compounded by future budget constraints on the appropriations share of the program or through unanticipated Agency costs. At that point, the Agency would have to choose between meeting the regristration schedule and program quality, a choice we cannnot afford. The Agency should be given wide authority to collect fees in the amounts it sees fit to cover the costs of the new pesticide program.

With the EPA's overall operating budget at 1977 spending levels it is clear that the money cannot be squeezed out of other Agency programs.

CITIZEN SUITS

The only major environmental statute without a citizen suit provision is FIFRA. S.1516 fails to contain such a provision. Farmers, other individual citizens and states should be able to help enforce the law or use it to protect their health and property. A citizen suit provision similar to section 505 of the Clean Water Act would allow citizens to sue the government or other violators and recover penalties as well. Our sagging pesticide policy needs this help in enforcement. Improved enforcement would also benefit law abiding businesses and individuals by reducing the number of cheaters who unfairly compete by violating environmental statutes. While some have argued that such a provision could "clog the courts," it should be noted that less than 200 citizen suits involving federal environmental statutes have been filed in the last six years.

RIGHT TO KNOW

S.1516 contains a right-to-know section that only covers active ingredient chemicals and only requires information from pesticide producers. FIFRA should contain a comprehensive right-to-know provision that fills the information gap left by the Superfund program. All communities need to know what chemicals are being stored, transported and used in their areas, and federal and state governments desperately need information on the patterns of chemical use to implement their groundwater monitoring and response programs. Such a program will also help reduce future costs and difficulties in identifying groundwater and food contamination.

The community right-to-know program established under the 1986 amendments to Superfund will be invaluable to emergency personnel, fire-fighters, plant workers and community residents in the event of chemical accidents in years to come. However, much of the reporting required regarding chemical inventories and emissions by storage facilities, transporters and large users will not apply to pesticides.

This information gap denies many rural communities the opportunity to properly prepare for accidents like the April 4 fire at a warehouse full of pesticides in Minot, North Dakota which resulted in the evacuation of 10,000 people. The lack of reporting about pesticide use would also deny state and federal regulators valuable information needed to control future ground and surface water contamination.

Pesticide labeling is also a right-to-know issue. Pesticide labels should be required to include full disclosure of chronic health effects of a product, as well as health effects not yet completely tested for, as recommended in the April 1986 GAO report, "Nonagricultural Pesticides: Risks and Regulation." The label should also include the listing of all inert ingredients, it is a scandal that they remain a "trade secret."

EPA recently published a list of "priority inerts," many of which are carcinogenic but are allowed to be used on food. While the Agency and Congress consider the restrictions on the use of these chemicals, the public has a right to know what products contain them. One of the food-use inerts on the Agency's list is methylene chloride, which the FDA recently banned as a propellant in hair sprays due to its cancer risk.

WORKER PROTECTION

People exposed to pesticides include hundreds of thousands of farmworkers, who are not protected by the Occupational Safety and Health Administration (OSHA), and additional commercial applicators of pesticides and their customers. According to the EPA, more than 1.5 million people have been trained to handle "restricted use" pesticides since 1978. The National Pest Control Association estimates that at least 1.5 million homes a year are treated by commercial applicators with termiticides (usually chlordane).

Clearly the people who harvest our nation's food deserve better working conditions than our current national policy provides. According to the Department of Labor, farmworkers suffer the highest rate of occupational injuries caused by exposure to toxic chemicals. Farmworkers and commercial applicators need strict worker protection standards as well as minimum training and certification requirements. S.1516 allows a double standard for applicators with farmworkers getting the lesser standard as usual.

To help ensure more responsible behavior on the part of employers and allow for compensation by employees, a 30 year record keeping requirement should also be incorporated into the worker safety provision. For example, EPA issued a final rule (40 CFR 763.121) earlier this year under the Toxic Substances Control Act (TSCA) to require employers to maintain records for 30 years for all asbestos abatement actions and to maintain employee medical records for 30 years as well. Many state right-to-know statutes have similar requirements. Because diseases with long latency periods, such as cancer, can be caused by exposure to toxic chemicals, it is essential that long-term record keeping be established under FIFRA. S.1516 only establishes a two year record keeping requirement for commercial applicators and none for farmworker protection.

Farmworkers and commercial applicators should also have strong whistle-blower protection. They are the most likely to notice a hazard but are unlikely to speak out if it means losing their job. OSHA has received 2,500 to 3,000 employee safety complaints a year in recent year's, according to a report this June by the Administrative Conference of the U.S. but farmworkers are still not protected under OSHA. Right now, FIFRA may be their best chance for protection.

PATENT TERM RESTORATION

The linkage of patent term extension legislation with pesticide reform was key to the negotiated compromise bill of last year. Such linkage ought to be clearly understood before connecting the two again this year. For a consumer organization it is no secret that compromising on such an important economic principle ought to be done only in exchange for a major gain in the area of public health and consumer protection.

Patent term extension could cost farmers $420 million to $500 million a year in lost savings on generic pesticides. Pesticides already represent more than 21 percent of a farm's expenses for products such as seed, fertilizer, fuel, etc. We are also opposed under any circumstances to the unjustified addition of bio-tech products to the patent term section of S.1516.

Questions Congress should seek answers to before embracing a patent term extension for pesticides include: Will such a change negate the streamlining of cancellation proceedings by giving manufacturers more of a stake in protecting their products? Will it discourage or delay innovation of safer alternatives? Is our public policy designed to ensure pesticide profits or to protect our health and environment with safe food and clean water?

CONCLUSION

There are those who may say that we are not demanding enough today in reforming our pesticide laws and history will likely prove them correct. However, we believe that the above mentioned improvements will make significant changes in the quality of public health protection from acute and chronic poisoning due to pesticide exposure. We also believe it is crucial that legislative language be as nondiscretionary as possible, otherwise loopholes will be exploited, as they are today, by the regulated as well as the regulators.

Additional areas that will someday need addressing include changing FIFRA's cost benefit standard to a purely health-based standard, mandating minimum use of innovative and alternative technologies such as Integrated Pest Management and non-chemical pesticide farming practices, and giving victims of pesticide contamination the right to seek compensation in federal court. The main reason we have not included those ideas in the body of our testimony is not because they do not merit immediate consideration but because we do not believe the Congress is yet willing to consider these ideas in detail. Environmentalists are continually told that if we advocate proposals that are "too strong," special interest groups such as the National Agricultural Chemical Association (NACA) will see to it that there is no FIFRA bill. And while environmental groups are urged to scale back on positions they have consistently held on other environmental bills over the past ten years, groups such as NACA have already raised the stakes by supporting liability exemptions and state preemption of food safety standards.

The priority issues discussed in the body of this testimony are strongly recommended modifications of provisions already contained in last year's bills, with the only exception being citizen suits which is contained in all other major environmental statutes. In other words, these proposals are very modest and deserve the most serious consideration of the members of this Committee and others in Congress.

Thank you for this opportunity to address the Committee on this crucial public health protection legislation.

U.S. Public Interest Research Group
National Association of State PIRGs

August 17, 1987

Senator Patrick J. Leahy
Committee on Agriculture, Nutrition,
and Forestry
328-A Russell Senate Office Building
Washington, D.C. 20515

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Dear Senator Leahy,

At your July 30 hearing on S.1516, pesticide legislation to reauthorize the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Senator Pryor asked the members of our panel to respond in writing to three questions. The questions were: what is your top priority for FIFRA reform? Is S.1516 a net improvement over this year's House bill H.R.2463? Do you agree that S.1516 is a net improvement over current law?

In response to these same questions earlier in the day, Ralph Nader recalled the story of a person who offers someone safe passage across a flooding river. But as the two reached the swelling river's edge the offer was withdrawn. When asked for an explanation, the person offering safe passage said, "well, I got you farther than you were before."

Even though S.1516 is a first step, it does not even represent a pier out onto the "river" we face today. To fully respond to the pesticide threat, a consensus about the urgency of the problem is needed. When Rachel Carson wrote Silent Spring 25 years ago, she sounded an alarm that has not been responded to by any of the three reauthorizations of FIFRA since. At the time, Ms. Carson was vilified by the chemical industry for exposing the dangers of pesticides. Today we know she was not only right but events such as the tragedy at Bhopal have dwarfed her warnings while pesticide use has since more than doubled. Yet, even 1987 proposals such as S.1516 fail to offer solutions that reflect the urgency of this unfolding health crisis.

Meanwhile, the pesticide industry has increased its influence through extensive lobbying and political action committee (PAC) contributions. Their interest in this legislation is not only self-serving but their denials of the dangers of pesticides, such as chlordane, are reminiscent of the claims of the cigarette lobby. However, the industry's priorities were clearly evidenced in their July 30 testimony by the amount of time they devoted to

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business issues such as data compensation. This is not entirely surprising in that none of S.1516 or even the current environmental proposals would have the effect of reducing overall pesticide use or require the use of alternatives to chemical pesticides. It is no wonder that opposition to past industry efforts to weaken FIFRA even further has consumed most of the limited resources of environmental groups.

In response to the first question regarding U.S. PIRG's "top priority," we find it impossible to choose between those of our members who may drink contaminated water, or eat pesticide laden food, or risk poisoning in their home or workplace due to pesticide use or production. Clearly everyone in these circumstances deserves much better protection than they are getting from the EPA or the FDA today.

Recognizing the widespread hazards associated with pesticide use and that the law to "control" pesticides (FIFRA) is among the weakest federal environmental statutes, U.S. PIRG has made it our top priority to strengthen FIFRA so that it is compatible with other major environmental laws such as the Safe Drinking Water, Clean Water Act and Superfund. Specific examples of improvements toward this end should include: a groundwater provision very similar to Representative James Oberstar's bill H.R.3174 which establishes a health-based standard without the loopholes contained in S.1419; a citizen suit provision patterned after section 505 of the Clean Water Act to allow enforcement by states and citizens against the polluters and the EPA; a right-to-know program that provides local governments and citizens with essential emergency planning information and gives consumers and applicators adequate health protection information about pesticides products and their use; and the cessation of all pesticide exports that are banned in the U.S. along with comprehensive monitoring of imported foods to prevent illegal and dangerous pesticide residues from entering U.S. food markets.

In response to the second question, is S.1516 an improvement over this year's House bill H.R.2463, the answer to this is not clear. For example, unlike S.1516, the House has not yet added a patent term extension provision on behalf of pesticide producers. And although House Agriculture Committee leaders have stated an intention to make their bill even weaker by adding amendments to preempt states authority to set food tolerances and to exempt large agricultural producers from clean-up liablility, environmentalists are opposing those proposals and seeking the adoption of strengthening amendments such as Representative Oberstar's groundwater bill H.R.3174, and an amendment to repeal indemnification and disposal obligations. However, should the House bill be sent to the Senate in the form it was last year (H.R.2482), it would not only be much weaker than your bill but it would be a weakening of current law and we would recommend that you strongly oppose it.

In response to the last question, is S.1516 a net improvement over current law, we would ask, what if the House does adopt a FIFRA bill as weak as they did last year? Will a relatively weak bill such as S.1516 allow the Congress to enact a new law that is truly stronger than current law? We believe the answer is no. Once a bill such as S.1516 goes to conference, no new agenda items will be germane. At best, the Senate may be able to take out damaging House provisions. Instead, two questions should be asked: How should FIFRA be changed to protect the public from the widespread exposure to pesticides? What can and should the U.S. Senate do to ensure this result?

By incorporating in your bill the changes recommended in our testimony, you will move Congress much closer toward addressing the public health threat now posed by pesticides. These same issues were outlined in a June 2nd letter to members of the Committee from 25 national organizations. The attached side-by-side summarizes these proposals and compares S.1516 with last year's House and Senate bills.

Thank you for this opportunity to respond to your questions. We look forward to working with you and your staff to assist in the reauthorization of a strong FIFRA.

Sincerely,

Rick Hind

Rick Hind
Environmental Lobbyist

July 1987

FIFRA (Federal Insecticide, Fungicide and Rodenticide Act)
Side-by-Side

ISSUE:	HOUSE BILL (October 16, 1986)	SENATE BILL (October 6, 1986)	LEAHY-LUGAR BILL (July 1987)	ENVIRONMENTAL POSITION
Food Safety:	Preempts state's authority to set more stringent food safety standards.	No similar provision.	Same as 1986 Senate bill.	No preemption of state's authority to set more stringent food safety standards.
Clean up Liability:	Exempts agricultural producers from clean-up liability under all federal environmental statutues.	No similar provision.	Same as 1986 Senate bill.	No liability exemption.
Ground-water:	Standards were based on costs of clean-up in a response program that does not require clean-up; fails to limit pesticide use until drinking water is already poisoned; leaves EPA's authority to require groundwater monitoring by chemical manufacturers open to legal challenge; and fails to fully address the protection of future drinking water supplies.	Similar to House bill but provides for response to contamination of future as well as current drinking water supplies.	No provision.	Prohibit the use and cancel registrations of pesticides with potential to leach into groundwater; give EPA and states authority and duty to require monitoring by pesticide registrants; use health-based standards (MCLGs) to establish ground-water residue guidance levels; address threats to future as well as current drinkiing water supplies; require manufacturers to pay for the clean-up of contaminated water supplies.

Registration & Cancellation:	Put Agency on nine-year beefed-up reregistration schedule but failed to close conditional and minor use registration loopholes, also failed to address off target pesticide drift or indoor contamination. Established a list of no more than 75 priority inerts for testing and regulation but did not require remaining 1,000 inerts to be evaluated in a timely manner or to be listed on label, allowed citizen standing in concellation hearing but shifted burden of going forward from registrant to public.	Same as House bill.	Same as 1986 House bill.	Establish accelerated nine year reregistration program and streamline cancellation procedures but also close loopholes such as conditional and minor use registrations. Require full labeling and testing of all inert pesticide ingredients. Establish drift and indoor exposure controls. Allow citizens standing in cancellation hearings with burden of going forward to remain the same as in current law.
Fees:	Levied approximately one-half the fees from pestcide producers needed to pay for nine year reregistration program.	Same as House bill.	Expects to raise $113 million of $150 million that EPA says it needs.	Adequate fees needed (at least twice last year's bill) to meet reregistration timetable.
Indemification/ Disposal:	Agency must notify Congress of all indemification obligations and merely "request" an appropriation.	Requires Agency to obtain line-item appropriations before making indemnification payments.	Same as 1986 Senate bill.	Repeal the requirement that EPA indemnify manufacturers of cancelled products and pay for their disposal costs.

Right-to-know:	Requires pesticide producers to report health information to public but exempts pesticide users and provides no mechanism to get information to communities.	Same as House bill.	Same as 1986 House bill.	Pesticide producers and users should make health information on pesticides fully available to all communities and employees through a systematic program similar to 1986 Superfund amendments.
Citizen Suits:	No provision.	No provision.	No provision.	Farmers, employees, citizens and states should have the right to sue government and private parties for enforcement of the law.
Exports and Imports:	Allows the export of banned and highly restricted pesticides as long as notice is given to receiving country. Required a ban on imported food with hazardous or banned residues but lacked adequate monitoring to be effective.	Same as House bill.	Same as 1986 House bill.	No exportation of banned or restricted use pesticides. Other pesticides should only be allowed for export to countries with equivalent or superior regulatory systems to U.S. Prohibit the importation of foods with banned or dangerous levels of pesticide residues and enforce through a comprehensive port monitoring program.
Worker Protection:	Farm workers would have weaker safety and training standards than commercial applicators. Only two year record keeping requirement and no whistle blower protection and inadequate enforcement.	Same as House bill.	Same as 1986 House bill.	Increase training and safety standards with equal standards for farmworkers and commercial applicators. Assure competency of commerical applicators. Require long-term (30 year) record keeping for health purposes, give protection to whistle blowers and require more strict enforcement of program.

Senator **Lugar**. The chair would like to recognize now David Baker and Shelley Davis who will be alloted 2½ minutes each. Mr. Baker is political director of Friends of the Earth and Ms. Davis an attorney with the Migrant Legal Action Program, Inc., and from the Committee in Support of Agriculture Workers.

STATEMENT OF DAVID K. BAKER, POLITICAL DIRECTOR, FRIENDS OF THE EARTH, WASHINGTON, DC

Mr. **Baker**. In the interest of time I would generally like to associate myself with the remarks of Mr. Hind in specific. We would concur fully with all the points that he made. The remarks that I would like to make specifically go to the point of the ground water bill, S. 1419.

We feel that that bill is a significant improvement over the agreements which were reached last year which led to the provisions which are currently in the House bill. One of the major differences is that this law would depend on the MCLG's rather than the MCL's. We feel that the MCL's are flawed as a method for setting ground water standards for a number of reasons.

Among those is that the MCL's are set with costs in mind. They are set as a standard for drinking water as treated by public and private utilities. Those standards, the MCL's which are set to be reviewed over time are driven by the cost of technology. It makes very little sense to us if residue levels of ground water standards would for some reason have to be altered as the MCL's are reviewed because the MCL's have been changed because of granular activated carbon filtering, for instance, which is used at plants, is suddenly made cheaper through some technological advent or through some economy of scale.

The MCL's have nothing to do with protection of ground water as a resource. The MCLG's which are a health-based standard have far more to do with that. The other remarks that we would like to make, in general, as regards FIFRA. Quite frankly, we think FIFRA is flawed beyond repair. The law itself is based upon two goals, goals to protect public health and a goal to also protect the markets of pesticide producers.

Unfortunately, to protect these markets that means allowing for increases in the use of pesticides. However, to protect public health, quite frankly what we have to do is reduce the amounts of these poisons that are introduced into our environment. To perform both goals cannot actually be done. As far as the current implementation of FIFRA, essentially what they do is allow for greater increase in pesticide use. We feel that three things should be done.

First, FIFRA should, in fact, be repealed.

Second, pesticides, chemical pesticides, toxic pesticides should only be used when they are proven to be essential, safe and effective.

Third, you should encourage alternate uses, the development of nonchemical alternatives for pest management.

[The prepared statement of Mr. Baker follows:]

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STATEMENT OF
DAVID K. BAKER, POLITICAL DIRECTOR
FRIENDS OF THE EARTH
BEFORE THE
COMMITTEE ON AGRICULTURE OF THE
U.S. SENATE

JULY 30, 1987

I am David Baker, Political Director of Friends of the Earth, the United States affiliate and founder of an international environmental federation with member organizations in 31 countries. Friends of the Earth sponsors an aggressive campaign of public advocacy and education on numerous issues including the international use, abuse and control of pesticides.

I would like to thank the Chairman and Committee for the opportunity to air our views on these important issues. In the interest of time, I will summarize my prepared statement, though I ask that it and several supporting documents be included in their entirety in the record.

Friends of the Earth (FOE) would be the first to admit to great difficulty and much struggling on decisions regarding reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Generally, our legislative activity has been guided by two goals. Our first mandate is to advocate adequate protection of public health. Second, we strive to encourage and realize the maximum protection of the public health and environment that is politically feasible within the framework of Congressional action.

FIFRA presents us with unusual problems. We find ourselves confronted with a situation where the maximum Congress is willing to do is inadequate to protect public health.

Such contradictions are typical of FIFRA. The law mandates the immediate banning of pesticides that are imminent hazards while calling for indemnification payments to industry which block this action. FIFRA bans these toxics for human exposure at home while allowing for exports of these poisons for human exposure overseas. Adding further adsurdity to this contradiction, the law sets up a framework for importing fruits and vegetables contaminated by these same illegal poisons back into the U.S.

Committed to the preservation, restoration, and rational use of the ecosphere

FIFRA's effects are contradictory becuase its programs are contradictory. FIFRA's programs are contradictory because its goals are contradictory. FIFRA purports to protect public health and also to protect industrial markets of pesticide manufacturers. Unfotunately, public health can only be adequately protected through decreased production of chemical pesticides and restrictions on the introduction of these poisions into the environment. On the other hand the industry demands (and has been able to achieve through the inaction of the House and Senate Agriculture Committees) protection of its markets, delays in any restrictions and encouragement of increased productions of pesticides.

FIFRA is simply flawed beyond repair. Even fundamental changes in its program such as the indemnification reforms in S. 1516 are mere band-aids on an open wound. Because of its inherent contradictions FIFRA has become a complex monster that is riddled with loopholes, fraught with delays and does not protect the public health and environment.

Yet, though FIFRA is complex, pesticide issues are simple. Congress must make a choice between protecting the public and preserving the profits of pesticide manufacturers. Pesticides are designed to kill. Pesticides are poisons. Only by limiting their use to cases where there is no alternative, only through limiting introductions of poison into the environment can we rationally and efficiently protect public health. We suggest a three-stage approach to pesticide management:

* Repeal FIFRA. As long as this is the basic law for protecting our health, the public can be assured that the foods they eat may kill them.
* Allow the use of a toxic pesticide only when it is proven that it is essential, safe and effective. The burden for controlling the introduction of these poisons into the environment must be shifted from public health to the profit-maker.
* Encourage the development of non-chemical alternatives for pest management. The current law not only encourages the use of toxic substances, but discourages the development and implementation of safer alternatives.

Though this framework represents a reasonable approach to protecting public health, we have been quite certain that it would not be adopted by recent Congresses. Though FIFRA has been amended several times over the years, it has not be substantially changed since 1972. Congress has been essentially paralyzed by the contradiction between the need to protect public health and the desires of the pesticide industry for a framework which allows for the growth of their profits.

To pick up the slack caused by Congressional inaction, representatives from the agricultural-chemical industry and public interests groups were forced to negotiate their own agreement for FIFRA reauthorization in lieu of Congress. This agreement failed last year due to disagreements between business factions and the addition by the House of several anti-environmental amendments which were outside of the negotiations.

Though Friends of the Earth endorsed the basic agreement reached in negotiations last year, we opposed the October 16, 1986 House bill. The virtual eradication of state authority to protect public health from pesticide residues on foods and the release from liability for polluters that merely follow the risk/benefit based label instructions for applications upset the delicate political balance that was achieved in that agreement. We applaud those Members of the Senate who held the line against the October 16th bill. The death of the final House bill was certainly a victory for public health. As the 100th Congress began, Friends of the Earth saw many reasons for not pursuing the political agreement that proved to be the basis for action in the 99th Congress. The primary reasons are substantive:

First, there is the problem of the federal preemption and liability release language that upset last year's agreement. Second, the 99th Congress produced new environmental legislation such as the Safe Drinking Water Act Amendments of 1986. The 1986 Amendments set up a new framework for federal and state activity to protect groundwater. The groundwater agreement from last year's negotiations is not consistent with the programs and provisions of the 1986 Amendments.

Third, new information has become available such as groundwater monitoring data showing widespread pesticide contamination in states such as Iowa and Minnesota. New studies were released on hazards from even the proper use of the termiticide, chlordane, and a recent National Academy Sciences report revealed new data on the relative carcinogenicity of pesticide residues on food. This information points to a need for new approaches that are not embodied in an unchanged bill.

Though these are subordinate to issue concerns, there are also several political reasons for not renewing the agreement in the 100th Congress.

First, public interest in the pesticide issue is growing. Pesticide are becoming a major political issue and hopefully will achieve public attention of the magnitude of programs such as the Superfund. A recent Washington Post Food Section article, subtitled "Reality and the Pesticide Issue" contained such quotes as, ... "be wary of 'perfect looking produce' which may hae been liberally sprayed" and "We can't wash everything all off of anything, but keep washing. Wash and write your congressman."

Last month's Harper's magazine contains in its index section of statistics a note that one-third of the pesticides that U.S. companies export are banned for use domestically. Pesticide articles, debates, and horror stories now appear in publications from U.S.A. Today to People magazine. This issue which once languished in a hidden world of political dealing and regulatory shadows is now entering the mainstream. As concerns about pesticides grow we are confident that Congress will respond with tougher laws.

Second, the public interest community has more resources to devote to pesticide issues with the completion of action on the Clean Water Act, Superfund and the Safe Drinking Water Act. These resources should increase public awareness and focus greater attention on programs like indemnification.

Third, the climate for strong FIFRA reform is better in the 100th Congress than in the 99th for a number of reasons.

Of this list, the primary reason for continuing to oppose the 1986 House vehicle are the substantive reasons. As the 100th Congress began, our organization made it clear in conversations and letters to Members and their staffs that if the October 16th bill was abandoned and the core agreement was restored without the killer issues of federal pre-emption and liability release, we would support such a bill and urge its speedy passage in the House. However, on May 19, 1987, HR 2463 was introduced with the clear intention of adding in federal pre-emption and liability releases. These provisions ruin a carefully crafted and balanced political agreement. They make a bill that was imperfect but marginally acceptable, politically unacceptable.

The contradictory nature of FIFRA forced us to accept many weak provisions in last year's agreement that did not provide adequate protection of the public. These include:

* Export provisions that allow pesticides deemed unfit for human exposure in the United States to be exported for human exposure in other countries.
* Standing provisions that limit public input in reregistration hearings for cancelled products and shift the burden of proof against public health.
* Citizens not having the right to sue EPA for violating the law. Such provisions are basic to all other Federal environmental laws.
* Right-to-Know provisions that do not cover all major sources of potential pesticide exposure and have inadequate public access to collected data.
* Inadequate worker protection, inert regulation, labeling, local authority and drift control provisions.

These flaws in the agreement point out the fundamental problem with FIFRA. It is not a public health protection law. FIFRA is a pesticide production law which on balance has done far more to protect the sale of pesticides than to protect public health.

The worst result of the whole process of FIFRA reauthorization in the 100th Congress is that no matter what bill is enacted, it will perpetuate the myth that FIFRA protects public health. The regulatory standard must be changed to make public health a priority. Proof of effectiveness of a pesticide, taking into account increased resistance of insects, must be required. Non-chemical alternatives for pesticide control must be encouraged. Even a bill which makes significant changes to the law, such as indemnification repeal, but does not address the fundamental problems of FIFRA, will still be a death warrant for a trusting public.

It is within the context of this view that we are making our judgments of FIFRA reform. We urge Congress to make as many improvements as possible and to educate the public about the areas where the reauthorization bills fall short. We will recognize improvements in the law, however, we will refuse to label partial change as reform. All bills introduced in Congress today and even the agreement reached between the public interest community and industry last year are fundamentally inadequate in their protection public health.

For example, the centerpiece of last year's agreement and much of this year's "reform" legislation is the acceleration of the reregistration process. Though better than the current law, it would have to be improved to adequately protect public health.

The reregistration acceleration contained in the S. 1516 is an improvement over EPA's current pace that wiil complete the process in 25 years. Yet, the accelerated schedule will not complete the process for almost a decade. Worse still, the fees imposed by this bill are not enough to complete this program in 9 years. The ultimate delay will be even longer.

Beyond these sad statistics is a point made by the National Academy of Sciences in a 1983 report. It pointed out that there are "no immediate solutions" to the problems of data uncetainty in making regulatory decisions because of the many gaps in our understanding of the causal mechanisms of carcinogenesis and other health effects. We hope that new reregistration evidence will spur EPA action, but given problems of a lack of resources, a limited mandate in the current law to protect public health and limited EPA authority to set policy within this Administration it is clear that accelerated reregistration is no panacea.

Congress has made it clear that given the power of the interests vested in FIFRA, patent term extension and the production of economic poisons, it has simply not been willing to protect public health from pesticides. This will change in time, as more people die, as consumers demand action, as farmers see their groundwater contaminated, but we are convinced it will take steps in this reauthorization and the next to complete the process.

Eventually, Congress will give the benefit of the doubt to public health rather than market convenience. Eventually Congress will place the burden of proof on the profiteers rather than on public health. However, it does not appear that this will happen in the 100th Congress. At this point the House Agriculture Committee seems poised to repass the flawed October 16, 1986 House bill. We are urging Members of the House to significantly improve this bill on the House floor.

The lead Senate vehicle, S. 1516, though inadequate in its protection of public health is an improvement over the current law. However, given the provisions of the House bill, which is weaker than the current law, it is even more crucial that the Senate bill be strengthened. At this point we urge Members of this Committee to support S. 1516 and to work to strengthen it at all points in the legislative process. S. 1516 must be improved by this committee or the full Senate Should S. 1516 fail to gain provisions adding hammers on the EPA reregistration deadlines and other provisions detailed in attachments to this testimony, we will urge the Senate and the House to stop work on FIFRA and wait until the next Congress to reauthorize this bill. Perhaps with further education of the public, additional changes in Congress and the advent of a new Administration, it will be possible to enact a reauthorization law which adequately protects public health.

Let me emphasize however, that we see no reason to shut down the FIFRA reauthorization process at this time and deny the public the chance at a full airing of these issues. We are hopeful that we can achieve changes to both the House and Senate bills that will bring these packages closer to minimal protection of public health. We stand willing to work with your staff to fashion compromises on the issues I have raised today. If FIFRA reform is to die it will not be because we refuse to compromise, it is because their are interests which do not want FIFRA subjected to public debate.

These statements are respectfully submitted by David Baker of Friends of the Earth as an addition to my testimony of June 30, 1987 in response to questions posed by Sen. Pryor.

1. What is your top priority for FIFRA reform?

A: Our long-term priorities for pesticide regulation reform are:

* repeal of the current flawed unreparable system of control embodied in the Federal Insecticide, Fungicide and Rodenticide Act.

* Curtailing the use of chemical pesticides unless they are essential, effective and can be used safely.

* Encouragement of the development of non-chemical alternatives for pest control management.

2. Is S. 1516 an improvement over HR 2463?

S. 1516 is certainly an improvement over HR 2463, but mostly because it embraces the principle of doing no harm. HR 2463 because of its authors stated intention to pre-empt state authority to regulate pesticide residue tolerances and to exempt pesticide polluters from liability is worse than the current law. S.1516 contains one significant improvement in the area of indemnification reform, but generally continues a status quo which does not adequately protect public health and endangers our agricultural economy.

3. Do you agree that it S. 1516 is a net improvement over the current law?

A: Yes, but only a marginal improvement. It does not address key questions of FIFRA's flawed regulatory standard, encouragement of integrated pest management and a host of other areas. It is very farfetched to call this package "reform".

FIFRA IN THE 100TH CONGRESS

Friends of the Earth endorses a three-prong strategy for dealing with pesticides.

1. Repeal FIFRA- the law is inherently flawed because of its weak regulatory standard, low funding and lack of an EPA mandate.
2. Restrict the use of a pesticide unless it is proven to be safe, effective and essential.
3. Encourage the use of Integrated Pest Management (IPM) and the development of non-chemical pesticide alternatives.

This ambitious but reasonable agenda cannot be obtained in the 100th Congress. Given this political reality FOE is working to improve the current law. However, we are not willing to accept a weakening or small improvement of the current law simply because Congress is unwilling to do more. FOE feels strongly that our role as public advocates is not only to achieve the maximum that is politically feasible, but to increase the maximum that is politically feasible. Despite the efforts to move the Agriculture Committees towards rationality, bills that are described as half a loaf are still merely crumbs.

SENATE BILL

Significant improvements-
Indemnification reform

Notable improvements-
Streamlines the special review process
Requires regulation of inert chemicals
Antimicrobial standards
Neurotoxicological test requirements
Revocation of tolerances for banned pesticides

Inadequate Improvements-
Fees are inadequate to pay for reregistration programs.
Right-to-know has inadequate coverage and inadequate means for dissemination of information to the public.
Export provisions are inadequate to stop shipment of banned pesticides for human exposures overseas.

Failed Improvements-
Reregistration acceleration has little value due to inadequate funding and lack of hammers if EPA does not follow schedule.
Worker protection language provides inadequate direction for EPA development of standards and inadequate 2 year record-keeping.
Groundwater protection provisions are not included.
Citizen suits are not included.
Clarification of municipal authority to regulate pesticides is not included.

Minuses-
Patent term extension- may spur development of biotechnology industry before proper regulations are developed.

HOUSE BILL

Significant Improvements-
None

Notable Improvements-
Streamlines special review process
Requires regulation of inerts
Neurotoxicological testing requirements

Inadequate Improvements-
Fees are inadequate to pay for reregistration acceleration
Right-to-know provisions provide inadequate coverage of major pesticide storers and methods of information dissemination to the public.
Exports provisions will allow shipment of banned pesticides for human exposure overseas.

Failed Improvements-
Reregistration acceleration has little value due to inadequate funds and lack of hammers for EPA inaction.
Worker protection language provides no direction for EPA standards and provides for only 2 years of record-keeping.
Citizen suits are not included.
Clarification of municipal authority to regulate pesticide use is not included.
Indemnification issue is not addressed.

Minuses-
Patent term extension- may spur development of biotechnology before proper regulation is developed.
Committee leadership has announced intention to pre-empt state authority to set pesticide residue tolerances.
Committee leadership has announced intention to release applicators of pesticides from liability under other environmental laws.
Groundwater provisions would allow pesticide contamination at levels that cause adverse health effects.

Summary:

1. House bill is weaker than the current law.
2. Senate bill is a marginal improvement over the current law.
3. Neither bill deals with the fundamental issues of FIFRA and pesticide control.
4. Unless the House or Senate or probably both bills are improved any conference will produce the status quo or worse than the current law.
5. Even if the strongest combination of both bills was enacted, FIFRA would still be inadequate to protect public health.

Senator LUGAR. Ms. Davis.

STATEMENT OF SHELLEY DAVIS, STAFF ATTORNEY, MIGRANT LEGAL ACTION PROGRAM, INC., WASHINGTON, DC

Ms. DAVIS. Senator Lugar, my name is Shelley Davis. I am an attorney with the Migrant Legal Action Program, Inc.

We appreciate the opportunity to address the committee regarding the health and safety needs of farmworkers.

Tens of thousands of farmworkers are poisoned each year in our Nation's fields due to exposure to pesticides. But no reliable data exists to document how many people have been injured, what products have harmed them, and what is the full, long-term extent of their injuries. In the absence of such statistics, EPA continues to permit the use of scores of pesticides which cause cancer, birth defects, sterility and other long-term chronic illnesses to the hardworking millions of farmworkers in this country.

In industrial settings around the country, it is now commonplace that workers are guaranteed a right-to-know what hazardous substances they are exposed to. Yet FIFRA provides no comparable protection for farmworkers. As a result, in virtually every State except California when a farmworker develops cancer or gives birth to a deformed baby, or develops some other chronic disease, neither she nor her doctors, can directly demonstrate that the illness is caused by a particular pesticide because the farmworkers are kept ignorant of the names of the products they are exposed to. In addition, they cannot turn to their employers for this information because private pesticide applicators, in other words, growers whose own employees apply the pesticides on their land, are not required to keep any records of the products they use.

We know that cancer often takes decades to develop. In order to be able to demonstrate the true toll of human misery caused by pesticide exposure, we need to require records be kept for 30 years to demonstrate the link between these illnesses and the pesticide exposure.

Workers in every industry but agriculture are protected by the Occupational Health and Safety Act. Under that act, workers' health and safety is protected to the maximum extent feasible. Farmworkers exposed to toxic pesticides deserve comparable protection.

Today EPA farmworker protection regulations fill a single page. We all know that the Federal bureaucracy writes volumes on subjects of far less significance. For more than 3 years already, the EPA has been working on revising these regulations, but to date it has not issued any proposal. Farmworker protection regulations are urgently needed, and they are needed today. But EPA's regulations will not be adequate unless they incorporate OSHA's standard and most adequately assure to the extent feasible protection of the health and safety of workers exposed to pesticides.

Thank you.

[The prepared statement of Ms. Davis follows:]

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TESTIMONY OF SHELLEY DAVIS, STAFF ATTORNEY, MIGRANT LEGAL ACTION PROGRAM, INC. BEFORE THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY ON S.1516, THE FIFRA REFORM OF 1987

Mr. Chairman, the Migrant Legal Action Program, Inc. appreciates the opportunity to address the Committee on behalf of our individual farmworker clients on the need to include provisions in FIFRA to adequately protect the health and safety of agricultural workers.

Approximately 300,000 farmworkers are poisoned each year in our nation's fields due to exposure to pesticides. But no reliable data exists to document the number of people who have been injured, which pesticides have harmed them and the long-term consequences of their injuries. In the absence of such statistics EPA continues to permit the use of scores of pesticides which cause cancer, birth defects, sterility and other serious chronic conditions to the 2,7 million hard-working American farmworkers who produce the food we need each day.

In industrial settings across the country it is now commonplace that workers are guaranteed a "Right to Know" what hazardous substances they come in contact with. Yet FIFRA provides no comparable provisions for farmworkers exposed to toxic pesticides. As a result, in virtually every state but California, when a farmworker develops cancer or gives birth to deformed babies neither she nor her doctors, can directly demonstrate that the disease was caused by exposure to a particular pesticide because farmworkers don't know what they have been exposed to. Nor can this information be readily obtained from the employer because private applicators -- whose own employees apply the pesticides, are not required to keep any records of pesticide applications.

We now know that cancer often takes decades to develop. Thus to demonstrate the true toll of human misery caused by pesticide exposure all pesticide applicators, both private and commercial, should be required to keep records of pesticide applications for 30 years.

Workers in every industry but agriculture are protected by the Occupational Health and Safety Act. The OSHAct requires the protection of workers' health and safety to the maximum extent feasible. Farmworkers exposed to harmful pesticides deserve comparable protection.

Today the EPA's regulations which are intended to protect the health and safety of farmworkers fit on a single page. We all know that the federal bureaucracy writes volumes on subjects of far less significance. For more than three years already, the EPA has been working on several worker protection regulations but to date none have yet been proposed. To be sure, new farmworker protection regulations are urgently needed -- as soon as possible. But the EPA's regulations will not be adequate unless they "most adequately assure, to the extent feasible," the protections of the health and safety of workers exposed to pesticides. In other words, farmworkers must be guaranteed by FIFRA, the same protection as the OSHAct provides to other workers.

In the absence of adequate action by EPA, a number of states have taken the initiative to protect the health and safety of farmworkers. These state laws must not be preempted by federal legislation.

Today, every decision by EPA on reregistration, registration, cancellation or suspension reflects a weighing of the costs in human suffering balanced against the industry's benefit in using the product. In the future such decisions should reflect a national policy to prioritize health and safety -- both of the men, women and children exposed to pesticides in their workplaces, and the health and safety of all of us who eat the food on which these substances have been applied.

In sum, pesticides are extremely dangerous chemicals and in reforming FIFRA, provisions must be added to protect the health and safety of farmworkers.

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August 19, 1987

Senator Patrick Leahy
Chair
United States Senate
Committee on Agriculture,
Nutrition and Forestry
328-A Russell Senate Office Bldg.
Washington, D.C. 20510-6000

RE: S. 1516

Dear Senator Leahy:

At the July 30, 1987 hearing on S. 1516, the Migrant Legal Action Program, Inc. was asked to respond to the following three questions: (1) what is the top legislative priority of the farmworkers we represent; (2) does S. 1516 represent a "net improvement" over this year's House bill, H.R. 2463; and (3) does S. 1516 represent a net improvement over current law. We appreciate the opportunity to respond to these questions and our answers follow.

1. What is the top legislative priority of farmworkers?

Farmworkers who are exposed to toxic pesticides throughout their working lives urgently request that FIFRA be amended to assure them protection which is comparable to that provided by the Occupational Safety and Health Act, 29 U.S.C. § 651, *et seq* (the "OSHAct"). Under the OSHAct, employers using toxic substances are required to keep records of the hazardous chemicals they use and their employees are guaranteed a "right to know" the harmful substances they have been exposed to. *Id*. at § 657(c)(2) and (3). In addition, the OSHAct directs the Department of Labor to set standards which "most adequately" protect the health and safety of workers "to the extent feasible." *Id*. at § 655(b)(5). Finally, workers in industrial settings who complain about safety violations are protected by the law from retaliatory discharge or discipline. Farmworkers deserve equivalent protection. Specifically, we request that FIFRA be amended to require that: (i) private applicatiors, as well as commercial ones, keep records of pesticide usage; (ii) that EPA issue regulations which "most adequately assure, to the extent feasible," the protection of worker health and safety; and (iii) that farmworkers who complain to EPA of safety violations be protected against discriminatory discharge or discipline.

2. Is S. 1516 a net improvement over H.R. 2463?

S. 1516 and H.R. 2463 both contain an important new training and certification provision which will increase the safety of many workers who apply pesticides. Nonetheless H.R. 2463 retains the requirement that EPA indemnify registrants for canceled products and its proponents have also expressed an intent to add a state preemption provision which would prohibit vital state regulation of pesticide usage. By contrast, S. 1516's modification of the current indemnification requirement and its exclusion of any state preemption provision make it a better bill.

3. Is S. 1516 a net improvement over current law?

Farmworkers are confronted by the inadequacies of FIFRA's protection on a daily basis. They are exposed to hazardous pesticides which should be banned, but remain in use; they are deprived of a "right to know" the substances they work with and cannot protect themselves from the hazards they pose; and they cannot rely on EPA for protection. These and other fundamental flaws in the current law can only be remedied by a significant overhaul of the existing statutory framework. The time is right for a significant change. The National Academy of Sciences' study and other revelations have heightened public awareness of the hazards posed by pesticides and aroused great interest in securing a solution. Second, much work has already been done by both houses of Congress towards passage of remedial legislation. As a consequence Congress has an historic opportunity to significantly reform FIFRA so as to adequately protect everyone exposed to pesticides -- in their workplace, through the food chain and in our drinking water. Unfortunately S. 1516 does not fulfill this historic mandate.

We again express our appreciation for the opportunity to address the Committee on this vital issue.

Very truly yours,

Shelley Davis

Shelley Davis
Staff Attorney

SD:mh

PROPOSED FIFRA AMENDMENTS TO PROTECT FARMWORKER HEALTH AND SAFETY

[Field Quarantine Period

7 U.S.C. § 136 will be amended by adding the following new § 136(k) and relettering all subsequent sections accordingly:

(k) Field Quarantine Period shall mean the period of time after the application of a pesticide(s) during which time no agricultural employee shall be permitted to enter the affected area to engage in routine agricultural practices (such as planting, weeding, hoeing, harvesting, etc.). The Administrator shall establish the field quarantine period for each pesticide which provides a sufficient period of time for the pesticide to degrade so as to prevent acute or chronic harm from the employee's exposure to the pesticide(s).]

Records

(Adopted from S.2792 with indicated modifications)

SEC. 401. RECORDS.

(a) IN GENERAL.--Section 8 (7 U.S.C. 136f) is amended to read as follows:

"(a) AUTHORITY TO REQUIRE RECORDS.--

"(1) IN GENERAL.--The Administrator, by regulation, may require any producer or exporter of pesticides, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, or commercial applicator, [or private applicator who employs five or more workers,] or any person who distributes or sells any pesticide--

"(A) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act;

"(B) to furnish to the Administrator reports stating the location where the records are maintained; and

"(C) to furnish a copy of any such record to the Administrator on written request.

"(2) RETAIL DISTRIBUTION OR SALE.--Except as provided in subsections (c), (d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain, or furnish any record under this subsection with respect to such pesticide.

"(b) LIMITATIONS.--The Administrator may not, under the authority of subsection (a), require any person to maintain records of--

"(1) financial data, sales data, or pricing data;

"(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure; or

"(3) research or test data (other than data relating to a registered pesticide, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).".

(c) RECORDS OF APPLICATORS.--

(1) COMMERCIAL APPLICATORS.--The Administrator shall require each commercial applicator [and each private applicator who employs five or more workers] to maintain records of each pesticide application, including the identity and quantity of pesticides applied and the date and location of such application for a period [to be determined by the Administrator of not less than] two years after each such application.

(Deletion of Private
Applicator Exemption)

(d) RECORDS OF PESTICIDE DEALERS.--

(1) IN GENERAL.--The Administrator, by regulations, shall require each pesticide dealer to maintain a record of each sale or distribution of--

(A) a pesticide classified for restricted use; and

(B) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

(2) Contents.--Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold.

(3) DURATION.--A pesticide dealer shall maintain the records required under this subsection for 3 years after the date of the distribution or sale.

(e) ACCESS.--

(1) EMPLOYEES, CUSTOMERS, AND COMPLAINANTS.--

(A) A pesticide dealer or commercial applicator [or private applicator] shall afford to an employee or former employee of such dealer or applicator access to records required to be kept under subsections (c) and (d) that directly relate to the employment duties of the employee.

(B) A pesticide dealer or commercial applicator, [illegible] shall afford to a customer [or employee or former employee of the customer] of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by such an applicator at the request of the customer or under a contract with a customer.

(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours, after the request is made.

(2) STATE AGENCIES.--A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 on request by such State agency to the commercial applicator [, private applicator who employs five or more workers] or dealer required to maintain such records.

(f) INFORMATION FOR EMPLOYEES.--An employer who uses or supervises the use of a pesticide shall--

(1) know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and to the safety, first aid, and antidote information listed on the labeling of the pesticide; and

(2) be responsible for promptly making such information available, on request, to any employee exposed to the pesticide and to treating medical personnel.

Worker Health and Safety Data Collection
and Requirements
(Adopted from H.R. 2580 as agreed
to by Farm Bureau with modifications)

WORKER HEALTH AND SAFETY PROGRAM

SEC. 25. (a) Section 25 (7 U.S.C. 136w) is amended by adding at the end the following:

"(e) WORKER HEALTH AND SAFETY PROGRAM.-

"(1)(A) The Administrator shall establish and maintain an occupational health program [. . .] for the protection of workers who mix, load, or apply pesticides or work in areas where pesticides are applied.

"(B) Such [program] shall--

["(i) evaluate data on adverse effects of pesticides on worker health and safety; and based on such data recommend to the Administrator, where appropriate, the initiation of an action for emergency suspension, suspension cancellation or special review of pesticide registration(s) or the imposition of restrictions on use;]

"(ii) develop and maintain expertise on working conditions and work practices of workers exposed to pesticides;

"(iii) participate in the development of regulations, standards, and registration data requirements relating to the health and safety of workers exposed to pesticides;

"(iv) evaluate registration, reregistration, interim administrative review, cancellation, [or special review] decisions [or other restriction(s) on use] with respect to effects of such actions on worker health and safety.

"(2)(A) The Administrator shall issue regulations which [most adequately assure, to the extent feasible,] the protection of [employees exposed to pesticides.]

["(B) The regulations shall require --]

"(i) the protection of employees who mix, load, or apply pesticides, including the use of --

"(I) protective clothing and equipment; [and

"(II) medical surveillance,] emergency medical care, and hygiene, and safe [field quarantine periods;]

"(ii) the training of each employee who mixes, loads, or applies a pesticide [concerning --]

"(I) worker health, public health, and environmental hazards [involved;]

["(II) safety procedures to be followed;]

"(III) clothing and protective equipment [to be used;]

"(IV) common symptoms of pesticide poisoning;

"(V) the location of emergency medical treatment; and

"(VI) applicable law, regulations, and label [ ] requirements [for each pesticide used; and

"(VII) employee's rights under the Act.]

["(iii) the protection of field and other agricultural employees who work in areas treated with pesticides, including --

"(I) field quarantine periods and posting requirements;

"(II) protective clothing and equipment;

"(III) information and supervision; and

"(IV) emergency medical care and hygiene; and

"(iv) the training of field and other agricultural workers concerning:

"(I) the pesticides to which the worker is exposed and the possible health effects;

"(II) safety procedures to be followed;

"(III) protective clothing and equipment to be used, applicable field quarantine periods and posting requirements;

"(IV) common symptoms of pesticide poisoning;

"(V) the location of emergency medical treatment; and

"(VI) label requirements

"(VII) employee's rights under the Act.

"(b) The amendment made by subsection (a) shall be implemented as soon as practicable but no later than 180 days after the date of enactment of this Act.]

Anti-retaliation Provision

(Adopted from TSCA with a slight modification)

"EMPLOYEE PROTECTION.-

"(a) IN GENERAL.- An employer may not discharge an employee, (or any person acting pursuant to a request of the employee) or otherwise discriminate against an employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, on the ground that the employee has --

["(1) or may have valid grounds to file a complaint under this Act;

"(2) contacted the employer, supervisor, union or other representative to report a possible violation of this Act;]

"(3) commenced, caused to be commenced or is about to commence a proceeding under this Act;

"(4) testified or is about to testify in any such proceeding; or

"(5) assisted or participated, or is about to assist or participate in any manner in such a proceeding or in any other action undertaken to carry out the purposes of this Act.

"(b) REMEDY.-

"(1)(A) Within 180 days after the occurrence of an alleged violation of this Act, an employee who believes that the employee has been discharged or otherwise discriminated against by an employer [or employer's agent] in violation of subsection (a) may file a complaint with the Secretary of Labor (hereinafter in this section referred to as the 'Secretary') alleging the discharge or discrimination.

"(B) Upon receipt of the complaint, the Secretary shall notify the person alleged to have committed the violation of the filing of the complaint.

"(2)(A)(i) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint.

"(ii) Within thirty days after the receipt of the complaint, the Secretary shall complete the investigation and notify in writing the complainant and the person alleged to have committed the violation of the results of the investigation conducted pursuant to clause (1).

"(iii) Within ninety days after the receipt of the complaint, unless the proceeding on the complaint is terminated by the Secretary on the basis of settlement entered into between the Secretary and the person alleged to have committed the violation, the Secretary shall issue an order providing the relief prescribed by subparagraph (B) or denying the complaint.

"(iv) An order of the Secretary under this subparagraph shall be made on the record after notice and opportunity for an agency hearing.

"(v) The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

"(B)(i) If the Secretary receives in accordance with paragraph (1) a complaint of a violation of subsection (a) and determines that the violation has occurred, the Secretary shall order the person who committed the violation to --

"(I) take affirmative action to abate the violation;

"(II) reinstate the complainant to the former position of the complainant, together with the compensation (including back pay), terms, conditions, and privileges of the employment of the complainant;

"(III) pay the complainant compensatory damages; and

"(IV) where appropriate, pay the complainant exemplary damages.

"(ii) If the Secretary issues an order described in clause (i), the Secretary shall, at the request of the complainant, assess against the person against whom the order is issued a sum equal to the amount of all costs and expenses (including attorney's fees) reasonably incurred (as determined by the Secretary) by the complainant for, or in connection with, the bringing of the complaint upon which the order was based and remit the sum to the complainant.

"(c) REVIEW.-

"(1)(A) Within sixty days after the issuance of an order described in subsection (b), an employee or employer adversely affected or aggrieved by the order may obtain review of the order in the United States Court of Appeals for the circuit in which the violation with respect to which the order was issued, allegedly occurred.

"(B) The review shall be conducted in accordance with chapter 7 of title 5, United States Code.

"(2) If an order of the Secretary is eligible for review under paragraph (1), the order shall not be subject to judicial review in a criminal or other civil proceeding.

"(d) ENFORCEMENT.-

"(1) if a person fails to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce the order.

"(2) A district court shall have jurisdiction to grant all appropriate relief (including injunctive relief and compensatory and exemplary damages) in an action brought under this subsection.

"(3) A civil action brought under this subsection shall be heard and decided expeditiously.

"(e) EXCLUSION.- Subsection (a) shall not apply with respect to an employee who, acting without direction from the employer of the employee, deliberately causes a violation of this Act."

Require Certified Applicators to Apply Restricted Use Pesticides

Training of Certified Applicators
(contained S. 2792)

7 U.S.C. § 136(e) is amended to read as follows:

(e) APPLICATOR.--

(1) COMMERCIAL APPLICATOR.--

(A) Except as provided in subparagraph (B), the term "commercial applicator" means a person (whether or not the person is a private applicator with respect to some uses) who--

(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use;

(ii) uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the business or work of the person; or

(iii) as an employee of a person described in clause (ii), uses or supervises the use of any pesticide.

(B) The term does not include a person who uses or supervises the use of a pesticide as described in paragraph (2).

(2) PRIVATE APPLICATOR.--The term "private applicator" means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity--

(A) on property owned or rented by such person or the employer of such person; or

(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) CERTIFIED APPLICATOR.--The term "certified applicator" means a commercial or private applicator who is certified under section ii".

(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.--Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if the pesticide is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed even though such certified applicator is not physically present at the time and place the pesticide is used.

7 U.S.C. § 136b(d) is amended by adding the following:

(d) USE BY COMMERCIAL APPLICATORS.--

(1) IN GENERAL.--It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is--

(A) a certified commercial applicator; or

(B) a registered commercial applicator under the direct supervision of a certified commercial applicator.

(2) CERTIFIED COMMERCIAL APPLICATORS.--To be considered to be a certified commercial applicator, a person, at a minimum, shall--

(A) have met the standards prescribed under subsection (a) and have received training--

(i) prescribed by the State agency, including training in the material referred to in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training programs prescribed under subsection (h);

(B) have had field, institutional, or industrial experience in pesticide use and application;

(C) have passed an examination prescribed by such State agency; and

(D) possess a valid commercial applicator certification issued by such State agency.

(3) REGISTERED COMMERCIAL APPLICATORS.--

(A) To be considered to be registered commercial applicator, a person, at a minimum, shall--

(i) have received training--

(I) prescribed by the State agency, including training in the material referred to in subsection (g); and

(II) conducted by a trainer who has met requirements prescribed under subsection (h); and

(ii) possess a valid registration issued by such State agency.

(B) A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

(e) USE BY PRIVATE APPLICATORS.--

(B) possess a valid private applicator certification issued by such State agency.

(1) IN GENERAL.--A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if the pesticide is applied by a person who is either--

(A) a certified private applicator; or

(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

(2) CERTIFIED PRIVATE APPLICATORS.--To be considered to be a certified private applicator, a person, at a minimum, shall--

(A) have met the standards prescribed under subsection (a) and have received training--

(i) prescribed by the State agency, including training in the material described in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training prescribed under subsection (h); and

(3) SUPERVISED PRIVATE APPLICATORS.--

(A) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction--

(i) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling; and

(ii) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

(B) The State agency shall require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A)(i) has been received.

(f) RECERTIFICATION AND REREGISTRATION.--

(1) IN GENERAL.--Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the state agency of such State of not more than 5 years.

(2) TRAINING MATERIAL.--The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14.

(3) RECERTIFICATION.--To be recertified, an applicator, at a minimum, shall meet--

(A) the requirements of subparagraphs (A),(B), and (D) of subsection (d)(2); or

(B) The requirements of paragraphs (1) and (2) of subsection (e).

(4) REREGISTRATION.--To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

(g) TRAINING MATERIAL.--

(1) DEVELOPMENT.-- The administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling.

(2) REVISIONS.--Within 12 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1987, the Administrator, in consultation with the Secretary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

(h) MINIMUM STANDARDS FOR TRAINERS AND TRAINING PROGRAMS.--

(1) TRAINING OF COMMERCIAL APPLICATORS.--

(A) The Administrator shall establish within 1 year after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1987--

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d); and

(ii) minimum standards for the training programs referred to in subsection (d).

(B) Training programs prescribed by any State under subsection (d) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period, the training program of the State does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

(2) TRAINING OF PRIVATE APPLICATORS.--

(A) The Administrator shall establish within 2 years after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1987

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e); and

(ii) minimum standards for the training programs referred to in subsection (e).

(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period the training program of a State fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period the training program of the State does not meet such standards, the Administrator shall prescribe the training programs referred to in subsection (e) for use in such State.

(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.--A State agency may approve any privately administered training program that the Administrator determines meets the more stringent of--

(1) requirements established under this section; or

(2) requirements established by the State agency.

(j) ENFORCEMENT OFFICER TRAINING.--Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, at a minimum, includes training covering materials specified in subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

(k) SEPARATE STANDARDS.--In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

(l) DEFINITION OF STATE AGENCY.--For purposes of this section, the term 'State agency' means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforcement responsibility or that does not have an agency designated under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.

Delegation & Cooperation

(Adopted from S.2792 with indicated modifications)

SEC. 2301. DELEGATION AND COOPERATION.

Section 22 (7 U.S.C. 136t) is amended by adding at the end the following:

(c) EFFECT ON CERTAIN OTHER LAWS.--(1) In exercising any authority under this Act, the Administrator shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. The Administrator and the secretary of Labor shall coordinate their effort to regulate pesticide use in the work place so as to avoid duplicative and conflicting regulation.".

["(4) In exercising their respective statutory authority, the Administrator and the Secretary of Labor shall coordinate the promulgation and enforcement of standards and regulations to ensure the protection of workers exposed to pesticides.]

Appropriations Provision

[(a) There is authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act for each fiscal year beginning with fiscal year ______; provided that, the Administrator shall allocate not less than $ ___________ to carry out the provisions of § 25(e) of the Act from sums appropriated each fiscal year to carry out provisions of this Act and other revenues collected pursuant to this Act.]

Senator LUGAR. Thank you very much, Ms. Davis. The chair would like to recognize now Ms. Franci Livingston, the staff attorney for Public Citizen, Washington, DC and Michelle Meier, counsel for government affairs, Consumers Union, Washington, DC. Each of you will be allocated 2½ minutes.

STATEMENT OF FRANCI LIVINGSTON, STAFF ATTORNEY, PUBLIC CITIZEN'S CONGRESS WATCH

Ms. LIVINGSTON. Thank you, Senator Lugar. We appreciate the opportunity to present our views today on S. 1516.

Few would have predicted in 1972 that we would be where we are today. In 1972, Congress effectively grandfathered hundreds of pesticides that lacked tests for cancer, birth defects and other hazards, but required EPA to reregister them. This program, which was to be completed in 1976, has been a failure. Not one of the more than 600 active ingredients used in pesticides has been completely reregistered.

We are pleased that S. 1516 builds on last year's FIFRA legislation by increasing reregistration fees. Expeditious completion of the reregistration process is the centerpiece of this legislation and increased fees are critical for that centerpiece to work.

While we realize that a single reform bill cannot remedy all the problems in the pesticide program, the bill, including the fee provisions, should be further strengthened by several important amendments. Congress Watch and Consumers Union have submitted a joint prepared statement. We will focus our comments on several areas that we see as integral to the workability of expedited reregistration.

First, we commend the sponsors of the legislation for including an important revision to FIFRA's indemnification requirements. EPA should not be required to insure registrants against products that pose an imminent hazard. Although we would prefer that the indemnification provision were deleted altogether, the advance line item appropriation represents a substantial improvement over current law. The growing information on the costs and potential costs of indemnification underscore that the current provision cannot be tolerated.

On a practical level, these costs will jeopardize the workability of the accelerated reregistration schedule by diverting critical Agency resources. Expedited reregistration is designed to speed the process by which EPA identifies and removes the bad actor pesticides from the market. This could be totally thwarted if, because of indemnification, EPA is straight-jacketed in the face of imminent health risks.

For example, EPA estimates its potential indemnification costs for dinoseb alone at $30 to $50 million. These costs could easily deplete the entire budget for the pesticide program which for 1987 is approximately $40 million.

Second, the current disposal provision places an unacceptable drain on EPA's resources. Section 19 of FIFRA mandates that EPA must accept pesticides that have been suspended and canceled for disposal at the Agency's expense. EDB disposal has already cost the

Agency $1.7 million. The Agency estimates that it will cost another $6 to $8 million and possibly up to $10.

Senator **Pryor** [presiding]. Pardon me, Ms. Livingston. Are you approaching the end of your statement?

Ms. **Livingston**. Yes.

Senator **Pryor**. Thank you. Your entire joint statement will be placed in the record.

Ms. **Livingston**. Obviously elimination of the indemnification and disposal provisions will go a long way toward making the centerpiece of the legislation reregistration work. The balance of our joint prepared statement will be presented by Ms. Michelle Meier.

Senator **Pryor**. Thank you very much, Ms. Livingston. Ms. Meier.

STATEMENT OF MICHELLE MEIER, COUNSEL FOR GOVERNMENT AFFAIRS OF CONSUMERS UNION

Ms. **Meier**. Thank you, Senator. Consumers Union also greatly appreciates the opportunity to testify on a very important piece of legislation. I will follow up on the earlier issues that Ms. Livingston pointed out to address two other issues that we consider critical to the centerpiece of the legislation, the expedited reregistration program.

First, there is the fee issue. Although we certainly commend the sponsors of the legislation for significantly increasing the fee levels that were in last year's FIFRA bill, we are terribly concerned that we are still facing a $37 million shortfall in the reregistration cost. We do not at all feel comfortable relying on increased appropriations for reregistration because over the past several years we have, instead, seen appropriations for OPP and EPA significantly decrease.

Also, we will be seeing other integral, crucial programs competing for increased appropriations during the same time period. For example, the bill does not include any funding for the increased numbers of special reviews and cancellation hearings that EPA will have to somehow finance.

We certainly believe that the shortfall should be made up by the industry itself. The industry has greatly gained since 1972 when Congress so generously enabled its members to become grandfathered to avoid—now it has been for 15 years—what the other pesticides had to face, the registration requirement.

One measure of that benefit can be viewed by considering what the cost is now for registering a pesticide. One company has estimated that that cost is $15 million. If you put that cost into 1972 dollars, and imagine, as is reasonable, that an industry member would invest that amount of money into some revenue producing enterprise, the company over 15 years, assuming a 6 percent return, would have made over $5 million. So, asking the registrants to fully fund the program at much less than $5 million, is, in our view, perfectly reasonable.

Our fourth point is also related to reregistration. And in fact, what it does is address the promise of the centerpiece of the legislation, that in 10 years' time or thereabouts we will not have any pesticides on the market that have not been reregistered.

So our proposal, which extends this promise to a guarantee, is that any pesticide that has not been reregistered at the end of the reregistration deadline be automatically canceled. We think that the consumers of the United States finally deserve the priority after 25 years. Thank you very much.

Senator **PRYOR**. Thank you, Ms. Meier. Do you have a written statement?

Ms. **MEIER**. Ms. Livingston and I have filed a joint prepared statement which will be in the record.

Senator **PRYOR**. Fine. Thank you very much for your statement.

[The prepared joint statement of Ms. Meier and Ms. Livingston follows:]

TESTIMONY OF

Michelle Meier
Counsel for Government Affairs of
Consumers Union

and

Franci Livingston
Staff Attorney
Public Citizen's Congress Watch

before the

Senate Committee on Agriculture, Nutrition and Forestry

on

S. 1516

The Federal Insecticide, Fungicide and
Rodenticide Act Reform of 1987

July 30, 1987

INTRODUCTION

Mr. Chairman and Members of the Agriculture Committee:

Congress Watch* and Consumers Union** appreciate the opportunity to present our views on S. 1516, the Federal Insecticide, Fungicide and Rodenticide Act Reform of 1987. We look forward to working with this Committee to achieve expeditious passage of effective FIFRA amendments this year.

FIFRA reform is critically needed and long overdue. In 1972, Congress required EPA to "reregister" all pesticides that lacked tests for carcinogenicity, teratogenicity and other toxicological effects. Today, fifteen years later, none of the more than 600 active ingredients used in pesticides has been completely reregistered. In the meantime, we continue to eat food that contains residues of inadequately tested pesticides.

Only recently the National Academy of Sciences released a report on the potential risks associated with just 28 food use pesticides. It estimated that over our lifetime these 28 pesticides alone could cause approximately 1.46 million additional cancers in the American population. The potential risk from these 28 pesticides may be only the tip of the iceberg. The NAS was forced to limit itself in this study to analysis of only 28 of the 53 food use pesticides currently identified by EPA as oncogenic or potentially oncogenic because information was not available to perform a comprehensive risk assessment of all 53 pesticides.

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* Congress Watch is the legislative advocacy arm of Public Citizen. Public Citizen is a nonprofit consumer research and advocacy organization, which works on behalf of its over 60,000 members nationwide.

** Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide information, education and counsel about consumer goods and services and the management of family income. Consumers Union's income is derived solely from the sale of Consumer Reports, its other publications and films. Expenses of occasional public service efforts may be met, in part, by nonrestrictive, noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports, with approximately 3.5 million paid circulation, regularly carries articles on health, product safety, marketplace economics, and legislative, judicial, and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

Moreover, the majority of pesticides used on food have never been thoroughly evaluated for their cancer risk. The EPA has examined only 115, less than half, of the pesticides currently registered for use on food for even the limited purpose of determining the quality or completeness of the oncogenicity data needed to assess the safety of their continued use.[1] Of these 115 pesticides, most of which were registered years ago without modern testing methods, only 23 percent had sufficient data to allow the agency to make sound conclusions about oncogenicity. Thirty-six percent had no adequate oncogenicity data on file.[2]

As you know, in the 99th Congress, our organizations as well as others negotiated with chemical companies and agricultural producers in an attempt to achieve compromise FIFRA legislation. Even though the Senate and House both approved bills that incorporated most aspects of the agreement, FIFRA reform died in the last days of the Congress as a result of controversy surrounding the "business issues" and amendments beyond the scope of the compromise. With that setback, the urgency of passing basic FIFRA reform legislation is all the more serious.

The Senate reform package in the 99th Congress, while no panacea, made significant progress toward improving a regulatory statute that has many fundamental flaws. It included accelerated reregistration schedules, pre-registration access to data, and revision of the indemnification provision in current law. These provisions from last Congress are a significant base on which to build in the 100th Congress.

This year we are encouraged by the fact that Chairman Leahy and Senator Lugar have introduced legislation that builds on that package by increasing reregistration fees. Expeditious completion of the reregistration process, originally scheduled for completion in 1976, is the centerpiece of the legislation, and increased fees is absolutely critical if that centerpiece is to work.

We are also pleased that the bill does not contain provisions that exempt agricultural producers from liability under the federal environmental statutes or that eliminate state authority to set lower limits for pesticide residues in food than those set by EPA. Last year, both of these amendments contributed to the failure of the FIFRA reform effort. These amendments were deleted from the Senate bill on the floor but unfortunately remained in the bill that passed the House on October 16. We oppose both of them.

While we realize that a single reform bill cannot remedy all the serious problems in the pesticide regulatory program, we believe that the bill, including the fee provisions, should be further strengthened by several important amendments. Our testimony focuses on the importance of the enhanced fee provisions, the indemnification provision, and recommendations for improving the bill. It also discusses our opposition to several amendments that may be offered, including liability exemption and uniform tolerance amendments.

II. THE FEE SCHEDULE SHOULD BE MODIFIED TO ENSURE THAT THE REREGISTRATION PROGRAM IS FULLY FUNDED AND THE LAW SHOULD GUARANTEE THAT NO UNREREGISTERED PESTICIDES ARE ON THE MARKET WHEN THE REREGISTRATION DEADLINE ARRIVES

S. 1516 establishes a reregistration schedule that, if all goes as planned, requires EPA to complete its reregistration responsibility within 9 years from the date of enactment. This reregistration schedule is the appropriate centerpiece of any FIFRA reform bill because the biggest problem facing us now is plain ignorance about the hundreds of pesticides that were grandfathered in 1972 when the reregistration requirement was first put into law.

However, any FIFRA reform effort that attempts to resuscitate the failed reregistration program must honestly assess the costs involved and guarantee that the money to support these costs is readily available. Unfortunately, the schedule is doomed to remain an empty promise if it is not supported by adequate reregistration fees.

The fee provision in the bill represents a significant and necessary improvement over the fee provision in the 99th Congress, for which we commend its sponsors. However, these enhanced fees are still not sufficient to cover the expected costs of the reregistration program.

Proposed Section 3(A)(j) of the bill sets fees by taking into account whether a pesticide was registered before or after 1978, since the older chemicals cost more for EPA to reregister, and whether annual sales from a pesticide are over or under $10 million. This provision is expected to generate approximately $113 million.

EPA estimates that the cost of the accelerated reregistration program will be approximately $260 million. Of course, some of the costs of reregistration can be born by the agency through the normal appropriations process. However, if history is any guide, this source of funding is grossly inadequate. EPA's current budget for its reregistration activities is a mere $12.3 million, which would produce only $110 million over 9 years. The combined contribution from EPA's budget and industry fees, then, will produce approximately $223 million. This means, that despite the enhanced fee provisions, there will be no certain source of funding for approximately $37 million of the estimated cost of the accelerated registration program. If the EPA cost estimates understate the actual costs, this shortfall will be even greater.

We are reluctant to rely on increased appropriations to compensate for this anticipated shortfall. There is no guarantee that these increased appropriations will become a reality. On the contrary, since fiscal year 1980 the EPA annual pesticide program budget has been sharply reduced.

Furthermore, it is important to remember that the reregistration program is likely to greatly increase the number of products requiring special review and cancellation hearings. Each special review alone can cost the agency twice the amount required for reregistration.[3] The bill does not generate funds to finance these integral costs, so they will be strongly competing with the reregistration program, as well as other pesticide and nonpesticide-related programs, for any increased EPA appropriations.

We believe the pesticide registrants for which this one-time program is necessary should be fully responsible for funding the entire program beyond that amount which one can confidently expect to be included in the regular EPA budget. These registrants have benefited for years, at the public's expense, by the incredible delays in EPA's reregistration effort. For years they have been able to make great profits in marketing their products while deferring the expense of health and safety testing, and avoiding the rigorous agency scrutiny that, in many cases, would likely have resulted in product cancellations or restrictions.

Although we anticipate the industry will argue that enhanced fee requirements will force many registrants to abandon their product, we believe these arguments are spurious. According to the 1987 House testimony of the Associate General of FMC Corporation, "(i)t typically costs a registrant company $15 million . . . simply to develop the extensive information required to support pesticide registration."[4] Assuming that the reregistration costs are comparable, fee levels that would fully fund reregistration cannot reasonably be viewed as the decisive factor in a company's decision whether to go forward with reregistration. If, on the other hand, reregistration costs are significantly lower than typical registration costs, then the industry would still have an incentive to go forward with reregistration even with fees that fully cover the reregistration program. This is because the costs of reregistration would still be significantly lower than the cost of new product development, which the EPA has estimated to cost an average of $25 million.[5]

These points become even stronger when one considers the fee schedule in the bill. First, fees are paid in increments over a five year period. Second, the reregistration fees will be shared among the registrants of each active ingredient according to market share, and there are an average of five companies for each active ingredient.

A fully funded reregistration program is justified because it would only require the industry to pay a miniscule percentage of its aggregate revenues from pesticide sales. EPA estimates that pesticides generate $6-7 billion in annual revenue. This amounts to $54 billion over the 9 year reregistration period. Thus, a one-time only reregistration fee that would make the program fully funded would only amount to a mere .3% of this total revenue.

Moreover, pesticide manufacturers would derive enormous benefits from the extended monopoly conferred by patent term restoration. The fees necessary to reregister their products under current scientific standards are dwarfed by this benefit.

We sincerely hope that any shortfall in reregistration program funding, whether caused by faulty cost estimates or insufficient fees, can be expeditiously remedied through the appropriations process so that the deadlines in the reregistration schedule will be met. However, we also believe that, at this late date, we cannot rely on hope.

More practically, we would like to rely on an amendment, which would be fully consistent with the promise of the bill's centerpiece, to require across-the-board cancellation of all pesticides that have not been duly reregistered by a fixed deadline. Particularly in light of the funding shortfall, the bill should include such an automatic cancellation provision that would become effective after the statutory reregistration deadline expires. At that time, many pesticides requiring reregistration will have been grandfathered for approximately twenty-five years, a full quarter of a century, and reregistration would be approximately twenty years overdue from the original target date of 1976.

This approach would finally implement a basic premise of public health policy -- namely that the public should not be exposed to a potentially hazardous product unless there is a reasonable degree of knowledge about its effects on human health and the environment. It will also spur the industry and the agency to vigorously join in any effort to get additional appropriations that may be needed.

III. INDEMNIFICATION AND DISPOSAL

A. INDEMNIFICATION

We commend the sponsors of the legislation for including an important revision of FIFRA's current indemnification requirement. The growing information on the costs and potential costs of indemnification underscore that the indemnification provision in the present FIFRA cannot be tolerated. EPA should no longer be required to insure registrants against losses from products that pose an imminent hazard.

On a practical level, these costs will jeopardize the workability of the centerpiece of S.1516, the accelerated reregistration schedule, by diverting critical Agency resources. For example, EPA has estimated its indemnification costs for Dinoseb alone at $30-$50 million.[6] These costs could easily deplete the entire pesticide program budget, which for 1987 is estimated at approximately $40 million.

The dinoseb indemnification cost estimates are only the tip of the iceberg. In response to a written request made to EPA by Senator Proxmire following a hearing of the HUD-Independent Agencies Subcommittee of the Senate Appropriations Committee on March 26, 1987, EPA stated that the suspension and cancellation of 2,4,5-T/Silvex carried indemnification costs of $18 million and that EDB has so far cost $2.4 million. In answer to these questions, EPA provided the following roughestimates of indemnification costs for six pesticides that could be subject to suspension and cancellation as the reregistration program proceeds:[7]

Pesticide	Estimated Cost
alachlor	$161.5 M
linuron	35.6 M
benomyl	78.0 M
daminozide	7.95M
methyl bromide	23.0 M
chlordane	53.2 M

Further, the current indemnification requirement jeopardizes the purpose of the reregistration program because it will deter the agency from acting on the information collected through the program. The expedited reregistration effort is designed to speed the process by which EPA identifies and removes the "bad actor" pesticides from the market. This public health purpose could be totally thwarted if, because of indemnification requirements, EPA is straitjacketed in the face of imminent health risks. As a matter of public policy, EPA should not have to face the spectre of indemnification costs when making public health decisions about whether to suspend a product from further use.

S. 1516 significantly improves the indemnification provision in the current law by requiring a specific line item appropriation of funds in advance of any indemnification payment. This provision, contained in Section 1301 of the bill, insures that indemnification costs do not jeopardize EPA's regular operating budget and therefore its ability to carry out its regulatory responsibilities. It also insures that indemnification costs do not act as a disincentive to suspension and cancellation actions. This same indemnification provision passed the Senate as part of the FIFRA bill in the 99th Congress.

B. DISPOSAL

Like the indemnification provision in present law, the current disposal provision places an unacceptable drain on EPA's resources and poses a disincentive against regulatory actions that are necessary to protect public health. Section 19 of FIFRA mandates that EPA must accept pesticides that have been suspended and cancelled for disposal. This disposal requirement presents technological problems and substantial expense for EPA. As currently interpreted by the Agency, Section 19 also requires EPA to bear the cost of storing suspended and cancelled pesticides and ultimately disposing of them. In pending litigation, a registrant is even asserting that FIFRA requires the Agency to bear the cost of transporting the cancelled pesticide to a location for safe disposal.

EDB disposal has already cost the agency \$1.7 million.[8] At the present time, EPA is in the first phase of the EDB disposal process, which involves emptying the pesticide from its present containers into storage tanks. Only about half of identified EDB stocks have been transferred to tanks so far. EPA still has to make a decision on the final method for disposing of EDB. The Agency estimates that EDB disposal will cost another \$6-8 million and possibly up to \$10 million.[9]

Similarly, Dinoseb, which was suspended in 1986 and is currently the subject of cancellation proceedings, could present disposal costs of \$30-70 million.[10]

There is absolutely no reason EPA should be responsible for handling and paying for the storage and disposal of suspended and cancelled pesticides. EPA should regulate proper storage and disposal but these tasks should be the responsibility of the pesticide industry. No other manufacturers of hazardous substances, to our knowledge, can shirk the responsibility for disposing of their own products on the government. In terms of equity, the party that marketed the product is the proper party to bear these costs. It is also in the best position to develop disposal technology for its particular product.

We believe that S. 1516 should expressly authorize EPA to require registrants to develop methods for safe storage and disposal as a condition of registration. We also believe that the bill should delete the current FIFRA provision that requires EPA to accept cancelled and suspended pesticides for disposal. EPA should instead be authorized to establish requirements for storage and disposal that are applicable to all holders of cancelled pesticides. Additionally, EPA should be given the authority to require a manufacturer to recall banned pesticides, and to properly store them. A recall authority would help to insure that banned pesticides are not simply dumped by end users who do not have the ability to properly dispose of the them.

IV. CITIZEN SUITS

All the major environmental statutes, with the exception of FIFRA, contain some type of citizen suit provision that allows citizens to enforce the statute. These provisions vary in scope but each at least provides both for suits against the government for failure to carry out a non-discretionary duty and suits against any person for violations of the statute. Ideally, we believe that FIFRA should contain a broad citizen suit provision such as that contained in the Resource Conservation and

Recovery Act (RCRA). RCRA not only provides for citizens suits for violations of the Act but also for suits to enjoin persons whose activities involving hazardous wastes cause or contribute to an imminent and substantial endangerment.

At the very least, FIFRA should be amended to provide for suits against the government for failure to perform a non-discretionary duty. This type of citizen enforcement provision would help to insure that EPA carries out its pesticide responsibilities in accordance with its mandate from Congress. Absent a citizen enforcement provision, statutory violations, including EPA's failure to follow the reregistration deadlines, could easily go uncorrected. This "minimal" type of citizen suit would only allow enforcement actions against the government, not against private parties and would not provide for recovery of damages. It should, however, require that the citizen suit be handled by the courts on an expedited basis since many times delay is the very thing that the litigation is trying to correct.

Such a provision is necessary because, under present law, there are sometimes difficult hurdles to jump to achieve "standing" to sue an agency even where the agency violates a mandatory duty. These hurdles are particularly difficult for public interest groups that are nonmembership organizations. Further, the law requires that even membership organizations must show that the agency's failure to act harms their individual members. Even though vast members of the public may be placed at substantial risk because of the agency's recalcitrance, this showing is not always possible for any particular plaintiff to make. In fact, if the agency's inaction broadly effects the public at large, the burden on the plaintiff could be even more difficult because a court may then decide that the injury is not particular to the plaintiff, and deny standing on those grounds.

PREEMPTION

We are pleased that S. 1516 does not in any way preempt state authority to establish stricter limits on pesticide residues in food than those established by EPA. As you know, in the 99th Congress such a provision was deleted from the Senate bill on the floor but unfortunately remained in the bill that passed the House on October 16. That same provision is in the FIFRA bill introduced this year in the House. We oppose any state preemption provision.

The state preemption provision, which is advocated by the food processing industry, infringes on the historic right of states, derived from the police power, to protect the health and welfare of their citizens. State authority to set lower tolerances than EPA has been exercised cautiously and only in instances of extreme health concern. Indeed, to our knowledge, states have acted to set their own tolerances in the case of only two pesticides, ethylene dibromide (EDB) and daminozide. These examples underscore the importance of retaining state authority in this area.

A. Daminozide.

Daminozide is a plant growth regulator used primarily on apples and peanuts. It acts systemically, which means its residues cannot be washed off or removed by peeling.

Tolerances for daminozide were first established in 1968. Five separate studies conducted between 1973 and 1984 suggested that daminozide and its breakdown product, UDMH (unsymmetrical dimethylhydrazene), are animal carcinogens. UDMH forms upon heating or processing foods containing daminozide residues. Infants and children are at the highest risk from daminozide and UDMH dietary exposure because they consume large quantities of apple juice, apple sauce and other processed foods. Additionally, the fact that children generate new cells at a high rate may make them more susceptible to carcinogens.

In September 1985, EPA proposed to cancel daminozide for use on food and concluded that daminozide should be classified as a "probable human carcinogen." Several months later, in January 1986, EPA rescinded this proposal after the Scientific Advisory Panel determined that the data available on the oncogenicity of daminozide were inadequate to perform a risk assessment. EPA is requiring additional test data on daminozide and though the Agency has imposed new use, application and tolerance limitations, the revised tolerance permits the use of daminozide on apples and other products at levels that have never been shown to be safe.

Last year, Massachusetts issued regulations to impose stricter limits on daminozide/UDMH residues than those set by EPA. The Massachusetts regulations significantly reduce and eventually eliminate residues for heat-processed apple sauce, apple juice and baby food.

B. EDB

EDB was registered for use on food crops in 1948. In 1975, the National Cancer Institute indicated that EDB was an animal carcinogen and a "probable human carcinogen." In 1977 further studies confirmed that EDB is oncogenic. That year EPA began a special review of the risks and benifits of EDB.

Six years after special review began, in September 1983, EPA suspended use of EDB as a soil fumigant after reports of groundwater contamination in California, Florida, Georgia and Hawaii. At that time, the Agency also proposed cancellation of EDB for grain fumigation and citrus use.

At the time of the 1983 suspension and proposed cancellation announcement, EPA did not limit EDB residues in food despite the Agency's estimate that dietary exposure to EDB in grains posed an increased cancer risk of 3.3 per 1000 individuals exposed. In response to EPA's inaction, some states established their own residue limits in order to protect their citizens. California, Connecticut, Florida, Maine, Massachusetts, Michigan, New York and Texas imposed zero tolerances (non-detectable level) for baby food products. Some states also set maximum residue standards for grain products, including ready-to-eat foods.

In February, 1984, EPA finally suspended grain fumigation uses of EDB and then established tolerances for grain products in April 1984, which allowed higher levels of EDB resides in food than the levels set by some states.

The Maine Department of Agriculture, in adopting stricter tolerances for grain than those tolerances set by EPA stated:

> The evidence suggested that excessive weight may have been given by EPA to the interests of the grain industry in minimizing the economic impact of any tolerance levels established. It was apparent that EPA's tolerance levels required minimal effort on the part of the industry to develop management techniques which would reduce levels of EDB. The record reveals that several such techniques are available, that some are already in use by some manufacturers and that EDB levels lower than those proposed by EPA can be, and in some cases, already are being achieved. For these reasons the Department has rejected the proposal that it adopt the EPA tolerance levels for the State of Maine.[11]

In testimony before a House Agriculture Subcommittee earlier this year, the Chief of the New York Bureau of Pesticide Management explained that New York established lower tolerance levels for EDB than EPA because 1) of differences in food consumption data, especially for children, 2) the combined exposure for air, water and food were examined together, and 3) the potential for adverse reproductive effects were examined in addition to the potential for carcinogenic effects.[12]

C. STATE AUTHORITY TO ESTABLISH LOWER TOLERANCE LIMITS SHOULD BE RETAINED

There are a number of reasons why a provision that restricts state authority to set lower tolerance levels than EPA should be rejected.

First, state authority has been exercised responsibly and only in compelling cases where the EPA has failed to act. There has been no demonstration of abuse at the state level to argue for a change in present law. Indeed, there are many pressures that deter states from setting lower tolerances except where there is a clear indication of high risk to public health.

Second, state authority has served as a critical check on EPA. For example, in the case of EDB, state action and investigation helped to force EPA to act after years of delay. Were independent state action precluded, states would have less ability to influence federal policy.

Third, in cases of extreme potential risk, states should retain the authority to err on the side of public safety where EPA decides to err on the side of the status quo. Indeed, even though the Federal Food, Drug and Cosmetic Act requires EPA to establish tolerances at "safe" levels in order to protect the public health and authorizes a zero tolerance for any pesticide when there is insufficient data to establish a higher level, EPA does not always use this authority, as demonstrated by the daminozide example. (See the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 346a(b); and 40 C.F.R. Sec. 180.5(a), authorizing a zero tolerance when "a safe level of the pesticide has not been reliably determined.") Where EPA choses not to follow this sound, Congressionally-sanctioned public policy, the states should retain the inherent authority to better protect their citizens.

Fourth, any uniform tolerance provision, however crafted, is likely to chill states' efforts to protect their own citizens because states would reasonably conclude that any actions they might take to achieve an exemption from a uniform tolerance would be futile. Even the compromise provision incorporated in the bill passed by the House on October 16 would have this effect. Under that provision, states would have the right to petition EPA for authority to establish a lower tolerance on the basis of special circumstances. It would be a rare case indeed where the agency would grant such a petition because that action would require the EPA to reverse its earlier determination that the uniform tolerance level was safe even for subgroups with special dietary habits.

VIII. LIABILITY

We are also extremely pleased that S. 1516 does not contain any provision that exempts agricultural producers from liability under federal statutes for costs of a response or damages caused by release of a pesticide into the environment. This type of exemption from liability (included in last year's House bill but deleted from the Senate bill on the floor) was one of the provisions that undercut the compromise agreement in the 99th Congress. We would oppose attempts to add a liability exemption to the present FIFRA bill.

We firmly believe that it is unfair to tie the passage of important FIFRA reforms to a provision that has no relevance to FIFRA. FIFRA itself imposes no liability on agricultural producers. The liability provisions of the Superfund law and RCRA, the law governing the disposal of hazardous wastes, were carefully crafted and subject to public debate at the time of their passage. Indeed, they remain subject to amendment in the appropriate context. Moreover, the proponents of the liability exemption have not put forth any information to show that agricultural producers have been unfairly burdened by the environmental statutes.

VII. CSMA DATA REQUIREMENTS AMENDMENT

The Chemical Specialties Manufacturers Association (CSMA) is seeking an amendment to FIFRA that would undermine any state efforts to require testing of pesticides under registration or reregistration programs. This amendment, which has been introduced in the House as H.R. 2869, has been euphemistically described by its proponents as a mere "synchronization" requirement. Much more, it would require EPA to promulgate regulations to "result in identical and concurrent data requirements" by all federal and state agencies. Thus, EPA would be required to establish data requirements and schedules that would preempt all state requirements. Consequently, for example, states would be precluded from implementing more expeditious schedules for reregistration than EPA or from requiring additional data beyond the data EPA requires.

We strongly oppose this amendment as an infringement on the historic authority of states to protect their citizens by requiring timely data on pesticides.

VIII. CONCLUSION

Other labor and environmental organizations are testifying today on the need for improved worker protection provisions, groundwater protection and restrictions on the export of banned and restricted pesticides. We urge these types of improvements as well.

We believe that effective FIFRA reform legislation should move forward without delay and are eager to work with the Committee toward that end.

Notes:

1. National Academy of Sciences, Regulating Pesticides in Food, (1987), p.51.

2. Id.

3. Interview with EPA staff. July 27, 1987.

4. Statement of Robert J. Fields, Associate General Counsel of the FMC Corporation before the Subcommittee on Energy and Agriculture of the House Committee on Small Business. June 24, 1987, p. 2.

5. EPA Notice of Proposed Rulemaking, 51 Fed. Reg. 42974, 42977 (Wednesday, November 26, 1986).

6. Response to Written Request from Senator Proxmire following a hearing of the HUD-Independent Agencies Subcommittee of the Senate Appropriations Committee on March 26, 1987.

7. EPA explained in its written answers to Senator Proxmire that these estimates assume 1) one-half of one year's production eligible for indemnification, 2) no stock carry-over from previous years, 3) that holders of these products make no other arrangements to sell or recycle stocks and 4) an average purchase price. The cost estimate does not include storage and disposal.

8. Transcript of testimony of Dr. John Moore, Assistant Administrator for Toxics and Pesticides of the EPA before the Subcommittee on Environment, Energy and Natural Resources of the House Committee on Government Operations, July 9, 1987.

9. Id. at 26, 45.

10. Id. at 50.

11. Regulation of Pesticide Residues, House Committee on Energy and Commerce, Subcommittee on Health and the Environment, (1986), p. 151.

12. Testimony of Marilyn DuBois, Chief, New York Bureau of Pesticide Management before the House Agriculture Committee, Subcommittee on Department Operations, Research and Foreign Agriculture, June 10, 1987.

RESPONSES TO QUESTIONS
FROM SENATOR PRYOR AT JULY 30, 1987
HEARING ON S.1516

SUBMITTED BY
MICHELLE MEIER
COUNSEL FOR GOVERNMENT AFFAIRS
CONSUMERS UNION
AND
FRANCI LIVINGSTON
STAFF ATTORNEY
PUBLIC CITIZEN'S CONGRESS WATCH

I. WHAT IS YOUR TOP PRIORITY FOR FIFRA REFORM?

The present FIFRA fails to protect consumers, workers and the environment from dangerous pesticides. While we realize that a single reform bill cannot remedy all the serious flaws in the pesticide regulatory program, we believe that S.1516 should be strengthened by several important amendments. Our highest priorities include:

* increasing reregistration fees to fully fund the program beyond that amount which one can confidently expect to be included in the regular EPA budget.

* requiring across-the-board cancellation of all pesticides that have not been fully reregistered after the statutory deadline expires. This amendment would be fully consistent with the promise of the bill's centerpiece -- the schedule for reregistering inadequately tested pesticides.

* deleting the requirement that EPA pay for disposal of suspended and cancelled pesticides and providing EPA disposal authorities as outlined in our testimony.

* deleting the indemnification provision in current law. Although we believe that the indemnification provision in S.1516 is a significant improvement over current law in that costs would no longer be paid from EPA's regular budget, we would prefer an outright repeal.

* strengthening the worker protection provisions to ensure that appropriate regulatory standards are set to protect worker health and safety and to require effective recordkeeping on pesticide use.

* a citizen suit provision that allows citizens to enforce FIFRA.

We also believe that S.1516 must not be weakened in any way. We oppose amendments that preempt the states from setting stricter limits on pesticide residues in food than EPA; undercut state registration and reregistration programs (proposed CSMA amendment) or exempt agricultural producers from liability under

Federal statutes.

II. IS S.1516 A NET IMPROVEMENT OVER THE HOUSE FIFRA BILL?

S.1516 improves upon the House FIFRA bill because it enhances the reregistration fees provision and because it significantly revises the indemnification provision in FIFRA. Both these improvements are important to the success of the centerpiece of the bill -- the reregistration program.

III. IS S.1516 A NET IMPROVEMENT OVER CURRENT LAW?

This bill should be evaluated based on whether it can truly solve some of the most pressing problems in the current pesticide regulatory program. The reregistration schedule is the appropriate centerpiece of S.1516 because the biggest problem facing us today is plain ignorance about the hundreds of pesticides that were grandfathered in 1972 when the reregistration requirement was first put into law. If the reregistration schedule is made truly achievable, then S.1516 will be a substantial improvement over the current law which promises reregistration but has never delivered it. The accelerated reregistration schedule, and the implicit promise that only adequately tested pesticides will remain on the market after 9 years, can only be accomplished if reregistration fees are adequate; EPA does not have to pay for either indemnification or disposal; disposal of cancelled pesticides is properly addressed; and pesticides not reregistered when the deadlines in the schedule expire are cancelled.

Senator **Pryor.** Mr. Feldman.

Mr. **Feldman.** Thank you, Mr. Chairman. Mr. Lugar, may I say that it was good to see you back in the chair for awhile there after all your hard work last year.

Senator **Pryor.** Senator Harkin is still in the Committee on Appropriations. He has an amendment, Senator Lugar, that he is trying to get adopted, so we are pitching in now for our friend, Senator Harkin.

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. **Feldman.** Thank you, Mr. Chairman. I would like to start by saying that S. 1516 is an improvement over last year's House passed bill, clearly in the areas of indemnification repeal, increasing the fees, although as the previous witness has indicated, it still falls short in areas that are of critical importance to us.

In addition, some of the measures in the House bill that make it unacceptable, such as preemption of State tolerance setting authority, limited liability for polluters and a weak codification of ground water protection standards. All those elements not being in S. 1516 is something we are very supportive of.

I was also pleased to hear Senator Boschwitz' testimony earlier today because what we are facing with the chemical chlordane is a nightmare. I think that is representative of what we are seeing perhaps across the board with numerous chemicals. Yesterday we sued the EPA in the Federal District Court to take emergency measures to ban chlordane, and we were joined by the American Federation of State, County, Municipal Employees, Friends of the Earth, Greenpeace, Izaak Walton League, because of the concern, particularly out in Indiana, the Northwest Coalition for Alternatives to Pesticides, People Against Chlordane, the Service Employees International Union, and the U.S. Public Interest Research Group.

What we are seeing over at the EPA at this point, and I might add to the embarrassment of many of the EPA staff that are very dedicated, is an example of how this law, with its discretionary authority, can allow products that offer tremendous amount of risk to stay on the market.

The goal that we are seeking, however, is to set in place a system that protects against pesticides overall. S. 1516 does not do this adequately on the whole. And the reason it does not do this is outlined in detail in our prepared statement, but let me for a moment tell you what our goal is and why we are having problems with the bill.

We would like to see pesticides regulated like other toxic substances. Clearly there are in discussions of pesticides some considerations that were discussed earlier by the industry about the value of pesticides, their contribution to production and so forth. I urge the committee to look very carefully at that issue because you will find, when looking back over last year we used over 110 million pounds of pesticides on wheat and corn to grow surplus commodities for which there was no market.

Is that a proper use of pesticides? What we are asking you to do in our testimony is something that a board member of ours from Kansas, actually Kansans for Safe Pest Control, has urged, and that is to craft a pesticide regulatory system that protects the environment along the lines of other environmental laws, such as RCRA, Superfund, NEPA (National Environmental Policy Act), the Safe Drinking Water Act et cetera. These are issues that are now being dealt with at the State level, and there are clearly six issues that we are asking you to look at in this regard.

First is the restriction on the use of pesticides in cases where they are simply not necessary, where alternatives exist. The bill does not address this issue whereas NEPA and Superfund or CERCLA does. In the area of the restricting of release of pesticides when they are used, a model bill would more clearly restrict the release of pesticides as nonpoint source solution such as RCRA does and the Clean Drinking Water Act and Clean Air Act.

A model bill would provide ecological and health-based standards, also provided for in other acts. A model bill would accomplish the above through considerations of alternative pest management strategies and all the costs and benefits of each which FIFRA does, but giving greater weight to public health and environmental cost benefits than economic cost benefits.

The burden of proof would be reversed. Pesticides could be released only if there were substantial risks of not using them and the risks of use are not excessive. These are elements that should be incorporated into a FIFRA bill which are not incorporated into S. 1516. Let me mention two others: the manufacturer and user would bear the burden of liability in recalls and disposal. This would repeal indemnification. And finally citizens would have the right to litigate an enforcement action. I realize my time is up.

I would like to say in closing that on the ground water issue we support the other witnesses that have come before us, and we urge you to take a very careful look at the cancellation proceedings under the existing bill which are long, lengthy proceedings after EPA has made a regulatory judgment that can put the public at continued and unnecessary risk. Thank you very much.

Senator Pryor. Thank you, Mr. Feldman.

[The prepared statement of Mr. Feldman follows:]

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
U.S. SENATE

JUNE 30, 1987

Mr. Chairman and members of the Subcommittee, I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP). I am here today on behalf of the members of NCAMP, a national, nonprofit, membership organization that represents community-based organizations and pesticide poisoning victims seeking to improve protections from pesticides and promote alternative pest management strategies which reduce or eliminate a reliance on pesticides. Our membership spans 48 states, Japan, Canada, Mexico, as well as other countries around the world.

We appreciate the opportunity to testify today because of the importance that the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) plays in the area of pesticide control. A weak FIFRA can allow for contaminated food, drinking water, and homes. A strong FIFRA can prevent contamination and the intrusion of poisons into our everyday life.

Unfortunately, what we have today is a very weak FIFRA, allowing pesticides, untested for a range of long-term health effects such as cancer, to remain on the market and in widespread use with inadequate health and safety data supporting their use. What is more, not only do these same chemicals remain on the market, but we allow actual expansion of use through provisions such as conditional and minor use registrations, and special local need and emergency exemptions. Then, we allow these materials, known toxins, to be applied in and around homes and schools by people who have virtually no demonstrated competence and often inadequate training.

When we finally do get around to regulating these materials, perhaps after determining the hazardous nature of the materials, the regulatory agency decides not to suspend uses because the law forces it to factor into the decision the sobering consideration that it must indemnify, out of its own budget, the regulated manufacturer for its losses and pay for the disposal of surplus stock. To make matters even worse, at the end of this process, the agency decides that continued use of surplus stock is the best method of disposal. A ban or "restricted use" status in the United States, of course, does not prohibit a manufacturer from shipping these materials abroad to harm people and the environment elsewhere. The "circle of poison" is complete when a foreign country uses the toxin in their agricultural production, and returns the residues to the United States on imported food.

Now, if there are aspects of the law that a member of the public determines are being violated under this weak law, that person is not provided any right to sue in an effort to enforce the law. Quite the contrary, people must rely on an enforcement system that is underfunded and operated, in most cases, by the very state agencies that are promoting pesticide use.

Mr. Chairman and members of the Committee. What we have here is the weakest environmental law on the books today. What we have here is a law that is so weak that it does not even deserve to be called an environmental law.

Pesticide use in pest management should be the exception rather than the rule. Alternative non-chemical approaches are now widely available. The pesticide control law should be written to regulate pesticide use as an exception, rather than the rule. The law should discourage the introduction of toxins into the environment, our food, our homes, and our workplaces. The law should regulate pest management, forcing detailed analysis of the range of non-chemical and low-chemical pest management strategies available, and the effectiveness of those approaches over time periods, measured against the real need for a commodity or service.

Under this strategy, it would be highly questionable to use toxins for landscape care, for example, since non-toxic alternatives are readily available and effective. Similarly, it would be inappropriate to use pesticides to produce surplus commodities. On the contrary, the existing pesticide law promotes pesticide use and serves to encourage manufacturers and users to enter the toxics market and enjoy the protections of this environmentally weak statute.

In spite of some of the facts that we intend to outline below, major weaknesses in the pesticide statute, as it exists now, continue to be ignored. The proposed reform bill, S. 1516, also continues to ignore them.

It is important to note that the pesticide law is less protective than other environmental laws in the standard of safety that it establishes for regulation. Pesticides are regulated under a risk-benefit standard, or a provision in the federal law that protects against "unreasonable adverse effects. . .taking into account the economic, social and environmental costs and benefits." By way of example, the Safe Drinking Water Act calls for the establishment of "maximum contaminant levels" at which "no known or anticipated adverse effects" occur and which allow an "adequate margin of safety."

While designed to ensure the availability of toxic materials as tools in food production or for use in combating a public health threat, the risk-benefit standard is of questionable value when alternative, less risky pest management approaches already exist and especially when a toxin is being applied for cosmetic reasons, such as the control of weeds in lawns. Clearly, the law allowed the use of 110 million pounds of pesticides on corn and wheat in 1986 to grow crops for which there was no market (1).

A Growing Body of Reports Illustrates the Pesticide Problem

Since the last public hearings before this Committee in 1986, Congress and the public have been presented with yet additional information on our weak national pesticide law.

In April, 1986, the U.S. General Accounting Office (GAO) reaffirmed earlier reports and findings of Congress and the National Academy of Sciences and reported that EPA "has not yet completely reassessed any active ingredient and issued a final regulatory position or standard." As of the end of the second quarter of 1987, EPA reports that the Agency has complete data for only 17 pesticides covered by 146 registration standards, which outline missing data necessary to complete registration.

Despite the current limitation of knowledge about the potential range of pesticide hazards, the GAO reports that, "The general public receives limited and misleading information on pesticide hazards." Survey work carried out by GAO finds that the public is regularly presented with information from pest control firms such as "every chemical. . .was rigorously tested for safety to applicators, customers, domestic animals, wildlife, and the environment." Others imply complete safety because, "Each of the materials [we use] is approved and registered for use on lawns by the Federal Environmental Protection Agency." In fact, advertisements are routinely distributed that maintain that EPA registration of pesticide products "is based upon the submission of scientific evidence to demonstrate that the product can be used safely and effectively." Until reregistration is complete, safety cannot be established.

The recently released National Reseach Council's report, Regulating Pesticides in Food, a study of 29 selected oncogenic chemicals used on food crops, concludes that there is widespread consumer exposure to oncogenic pesticides through the food supply. The data indicate an unacceptably high level of risk under any standard.

As you may know, Mr. Chairman and members of the Committee, the experience of the National Coalition Against the Misuse of Pesticides (NCAMP) reflects a concern that is not merely theoretical. We are in touch with people on a daily basis who suffer under this weak statute. Unsuspecting people have had their lives destroyed by contamination incidents. Therefore, it behooves us to analyze in its entirety, the impact of the legislation that you are considering, S. 1516 and related amendments that are before you.

S. 1516 in Review

S. 1516 is more notable for what is does not do than for what it does. However, I would like to start with the one critical improvement that the bill does contain.

Paying Manufacturers When Their Products Are Regulated

As you know, the practice of government paying manufacturers whose products are suspended the market value of all surplus stock and then requiring EPA to pay for disposal costs is unacceptable for numerous reasons. First of all, taxpayers do not share in the profits of the chemical industry and therefore the public does not share the associated financial risks. While investing in the chemical industry is highly profitable, it is also highly risky. These risks must be borne by the industry, not the public. Second, the disincentive for EPA action that indemnification brings with it results in decisions that that are not protective of public health.

This country is now living through a nightmare that many EPA officials tie directly to the indemnification provision. Yesterday, we sued EPA in U.S. District to seek an immediate, emergency, suspension of all uses of the termite insecticides chlordane, heptachlor, aldrin and dieldrin. In March, NCAMP formally petitioned EPA to use its emergency powers to protect the public because of what has been identified widely as the imminent harm associated with the widespread use of these chemicals.

EPA officials have reported that they will not use the Agency's emergency powers to take the products off the market, citing the indemnification provision. EPA says it lacks the estimated $53 million it would cost the Agency to pay for the producer's six-month inventory, not including additional costs for disposal.

S. 1516 will correct the disincentive now built into FIFRA. It will leave open, however, the possibility that taxpayers will pay manufacturers for their losses and disposal costs.

Inadequate Fee Structure Threaten Reregistration

While S. 1516 makes some progress toward meeting the costs of reregistration, we are worried, frankly, that the reevaluation of product safety will be undermined by a serious lack of funds. It is pointless to set up an elaborate scheme for reregistration of untested pesticides with deadlines and the like, if the administering agency does not have sufficient funds to meet the task at hand. In fact, the fee structure provided for in the bill does not raise sufficient revenues for EPA to meet the imposed deadlines for reregistration of pesticides. Thus, it is not clear that the centerpiece of the legislation, accelerated reregistration, could ever be fully implemented.

Groundwater Protection Codifies Weak Standard of Safety

The groundwater protection bill, S. 1419, now before this Committee is very troubling in that its attempt to protect groundwater may actually be doing more harm because of an inadequate standard of safety, with unacceptably high rates of cancer attached to individual contaminants. Legislation is needed to keep pesticides out of groundwater, not allow contamination up to some rate of cancer that Congress deems is acceptable. We do not believe that the public wants to drink carcinogens and we do not want to believe that this Committee wants to vote to ensure that.

The bill has in it a provision that will no doubt be used to delay, perhaps indefinitely, the regulation of hazardous groundwater contaminants. Under the bill, the Administrator is afforded the opportunity to delay action on a groundwater contaminant if the alternative pest control is determined to be more dangerous. We are dealing today with a spectrum of chemicals, one more dangerous than the next, but all well beyond the threshold of safety. Unfortunately, the only way to move agriculture away from these materials toward alternative methods of pest management, including more enlightened cultural practices, is to eliminate these "bad actors" one by one in the order that sufficient data becomes available. EPA decision makers should not be held hostage to the next worst chemical, but should be empowered to move expeditiously and without hesitation.

This Committee is aware, of course, that EPA has found 23 different pesticides in the groundwater of 24 states. The state of California alone reports 57 pesticides in the groundwater of 28 counties. Action is long overdue and S. 1419 needs serious improvement.

Use Exemptions Undermine Reregistration

Added to the list of problems is the fact that the bill provides avenues for pesticide registration that undermines the very reregistration program that people agree needs fixing. The "minor use" exemption, the "special local need" exemption and conditional registration overall, allow for expanded use of products that may exceed risk criteria or have incomplete health and safety testing data.

The Risk-Benefit Standard Is Not Protective of Public Health

The compromises contained in the so-called "negotiated" FIFRA bill, negotiated between the chemical industry and environmental groups, never represented the ideal pesticide control bill. The preferred language would bring pesticide law into conformance with other environmental laws requiring health-based regulation of toxic materials, as opposed to the bill's risk-benefit standard. It would also provide citizens involuntarily exposed to pesticides with a private right of action or an improved method of enforcing a very badly enforced law, a provision also basic to all other environmental laws.

Are Unacceptable Senate-House Compromises on the Horizon?

It is our understanding that many, perhaps the majority in the Agriculture Committee, would be satisfied to compromise to the FIFRA reauthorization bill (H.R. 2482, October 16, 1986) that passed the House last year. Those who endorse this approach unfortunately overlook some very serious deficiencies in the legislation that passed the House last session.

State Tolerance Setting Authority Threatened

If the House Agriculture Committee has its way, the Senate will be presented with legislation that will require the public to relinquish current state authority to adopt more stringent food safety standards than the federal government. Above all and despite the high degree of regulatory uncertainty, one thing we may certainly expect: EPA will be challenged from time to time on its findings or regulatory position even after completion of a regulatory review. We have found this over the years to be true. Clearly, in the case of ethylene dibromide (EDB), the state of Florida found EPA's actions unprotective and moved to protect its residents. Other states followed and EPA learned something in the process. The Agency learned that the regulatory course it was pursuing and had publicly announced was flawed and then decided to follow the lead of those states that had acted when it ultimately issued an emergency suspension. This is a prime example of the usefulness of state involvement.

Last year's House October 16th bill stifles state involvement. Given our experience with EPA, it is virtually unthinkable that EPA would respond positively to petitions from states seeking exemptions from the federal standard. Once established, there would be virtually no incentive to allow deviations from the "uniform tolerances" advocated by the food manufacturing industry. Indeed, the entire process is set up to inhibit community involvement and citizen participation. This would undermine public trust and faith in the Agency nationwide, and leaves the entire country all the worse off.

Limited Liability for Contamination by Farmers

Similarly, if the House Agriculture Committee has its way, the Senate will be presented with a bill that allows registration of materials that are known to have risks, while users of toxic pesticides will be exempt from any responsibility for harm resulting from use. To exempt farmers or any other user group from liability would release users of a burden to choose responsible pest management practices. For instance, it is not responsible at this point in time to use materials that are known to leach into groundwater simply because EPA has not yet upgraded product labels or because a determination was made that the benefits of use outweighed the risks of leaching. To release users from liability would increase the irresponsible use of products. To release users from liability without specifically assigning responsibility would leave those damaged without recourse.

On Balance, the Senate Bill With Any Unacceptable House Provisions Is a Step Backward

When we stack preemption of state authority up with inadequate funding to meet imposed reregistration deadlines and add to it disincentives for EPA action to suspend and cancel deadly materials with a whole set of additional provisions, the total package is a step backwards rather than forward.

When pesticide regulation is further clouded with a bias to maintain the market life of toxic materials that have safe alternatives (including pest control methods and newer pesticide products), we further weaken the law.

What Would Reform Look Like

Unfortunately, the concept of reform is basically foreign to the deliberations of this Committee when it comes to FIFRA. An NCAMP board member from Kansas, Ms. Terry Shistar, with Kansans for Safe Pest Control and the Sierra Club, has outlined an invitation to this Committee to consider the dimensions of reform. Reviewing the issues that follow will give you further insight into why we feel that the legislation before you today, S. 1516, is remiss in not addressing head-on the improvements so desperately needed to protect the public and the environment from the dramatic contamination and poisoning that now plague our nation.

Although Rachel Carson's Silent Spring has been said to have ushered in the era of environmentalism, pesticide reform has been largely an orphan issue. Those who work on pesticide reform, mostly address the issue outside of the context of other environmental issues such as clean air, clean water, and hazardous wastes. The fact that we address toxic pesticide issues under the jurisdiction of the Agriculture Committees, almost exclusively, is testimony to this fact.

Perhaps this is largely because we have let the existing system of regulation set our frame of reference. FIFRA is not an environmental law as much as a law for settling disputes among manufacturers. State pesticide laws, as well as FIFRA, are generally referred to agriculture committees, rather than to the environment committees that deal with environmental legislation. Pesticide regulation is generally placed in agriculture departments rather than in departments of environmental protection.

The time has come to change the way this Committee and the nation regulates pesticides, to make pesticide regulation consistent with regulation of other environmental hazards.

A Short History of Pesticide Regulations

Pesticides have been regulated in this country since the passage of the Insecticide Act in 1910, which sought to protect consumers from ineffective products and deceptive labeling. But it was not until 1947, after the development and usage of pesticides had received a boost from World War II, that Congress passed the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which required that pesticides in interstate commerce be registered with the U.S. Department of Agriculture. FIFRA was still concerned mostly about efficacy rather than safety, and was unenforceable because the Secretary could not deny a registration, there was no regulatory control over use, and the Secretary had the burden of proof to show the product was unsafe or ineffective.

In 1964, FIFRA was amended to permit the Secretary to deny or cancel a registration and require the registrant to submit proof that the product is safe and effective. However, it was not until shortly after the Environmental Protection Aency (EPA) was formed in 1970 that uses of pesticide containing DDT, 2,4,5-T, and aldrin-dieldrin were suspended and cancelled in response to suits from environmental organizations.

In 1972, amendments to FIFRA allowed EPA to classify pesticides for general use or restricted use by certified applicators and included penalties for misuse of pesticides. The 1972 amendments also gave some trade secret protection and provided for reimbursement of original registrants for use of test data in additional registrations of products with the same active ingredients. In addition, the amendments require EPA, as you know, to indemnify registrants and other who possess cancelled or suspended pesticide products, prohibits EPA from denying a registration because of nonessentiality, and extended federal authority to intrastate use and distribution of pesticides.

FIFRA was amended in 1975, 1978, and 1980, but the structure has remained the same since the 1972 amendments. Thus, federal pesticide registration has moved from protection of consumers to protection of manufacturers, while occasionally giving attention to public health and the enviroment.

FIFRA vs. Environmental Legislation

There are several areas where pesticide regulation under FIFRA differs dramatically from toxics regulation under other federal statues:

(1) Standard of safety: FIFRA, in defining "unreasonalbe adverse effects on the environment," explicitly allows environmental and health risks to be weighed against economic benefits. In contrast, most other statues (e.g., Clean Water Act, Safe Drinking Water Act, etc.) forbid actions that endanger public health and can be avoided.

(2) Although the pesticide registrant has the burden of showing that the proposed use of a pesticide does not pose unreasonable adverse effects to the environment, there is a presumption of benefit or need built into the statute. If the pesticide kills pesticides (or even if it does not, since efficacy data is usually

waived), there is a presumption in favor of registration unless the unreasonable adverse effects trigger is met. Contrast this with the National Environmental Policy Act (NEPA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), for example, where there is a burden to examine all alternatives and choose the least damaging one if practicable. The presumption of need provides a built-in bias in favor of dependence on chemicals in pest management.

(3) Action to remove a pesticide from use is not triggered by environmental contamination. In contrast, if water quality standards established under the Clean Water Act (CWA) are exceeded, for example, then permits for discharges can be denied or revoked.

(4) Citizens may not sue for enforcement of FIFRA as they may for violations of other statutes.

(5) If a pesticide registration is cancelled because it poses unreasonable adverse effects on the environment, EPA must indemnify the manufaturer for remaining stocks and dispose of the pesticide. This public expense is not required under any other environmental or consumer protection statute.

(6) FIFRA allows unpermitted, uncontrolled release of toxics into the environment, while all other environmental statutes seek to restrict the release of toxics to a minimum.

What are Economic Poisons?

Pesticides were once referred to as "economic poisons." As poisons, they received special consideration under the law because they were useful in protecting food crops and other things of economic value from pests. However, as we have recently come to recognize that a much wider range of chemicals used in economic enterprises are toxic, we have created or amended environmental legislation such as the Resource Conservation and Recovery Act (RCRA), Safe Drinking Water Act (SDWA), Toxic Substances Control Act (TSCA), CERCLA or Superfund, Clean Water Act (CWA), and Clean Act (CAA) to regulate the manufacture, disposal, and release of toxic materials used in business. Materials such as polychlorinated biphenyls, cadmium, and trichlorethylene all have the same claim to the name "economic poisons" as pesticides.

When pesticides are judged in the same terms as other economic poisons, they lead the field in risks posed to public health and the environment. EPA recently performed a risk assessment of risks posed by hazards under their jurisdiction. The risks posed by pesticide use were much greater than any other environmental hazard.

What makes pesticides different from other economic poisons? The major difference is that in general it is unnecessary to prove that pesticides are toxic --they are designed to be poisons. In addition, pesticides are generally used by broadcasting them into the environment, whereas most economic poisons are released accidentally or through disposal.

Why do we tolerate the purposeful disperal of poisons into our environment? We have been convinced that we need to broadcast poisons in order to produce food, protect our homes, and reduce nuisances. In fact, we do not need to broadcast poisons in order to control pests. Furthermore, the regulatory structure of FIFRA never did restrict the use of pesticides to those cases where they are needed, or in any respect the best alternative.

The above claim will be central to real pesticide reform efforts: We do not need to broadcast poisons in order to control pests. This point has been emphasized by Sheila Daar, Executive Director of the BioIntegral Resource Center (BIRC) in Berkeley, CA. BIRC does research on integrated pest management (IPM) strategies and acts as a consultant in implementing IPM. As researchers, BIRC's staff reviews about 400 articles per month on advances in biological approaches to managing pests. Ms. Daar reports that in its role as a consultant, BIRC has dealt successfully with virtually every pest problem in every setting --from parks to agriculture to homes. "Successfully" to BIRC means three things: (1) The pest population was reduced below the appropriate threshold level (economic, aesthetic, etc.); (2) A minimum of toxic material, if any, was used in a controlled manner; and, (3) The cost of managing the pests was lower than it would have been if convention chemical controls had been used. We can no longer point to a lack of research in IPM --we merely lack a comprehensive implementation program.

The Future of Pesticide Reform

Now that we are faced with the realizations that pesticides are only one class of economic poisons and that we do not need to give them special treatment, we should undertake major revisions to bring FIFRA into line with environmental statutues. What should pesticide reform legislation look like?

First of all, in recognition of our country's prolonged dependency on chemical solutions to pest roblems, pesticide reform legislation should contain, along with major changes in the regulation of pesticide manufacture and use, a large-scale campaign against chemical dependency --an outrech program to teach people to analyze pest problems in a systems context and seek the most environmentally sound solutions.

To help craft a pesticide regulatory system that protects the environment, we will need to draw on the wealth of experience with legislation such as RCRA, Superfund, NEPA, SDWA, and so forth. Some aspects of a law would be:

(1) It would restrict the use of pesticides to cases where they are necessary, after considering all alternatives, in order to avoid a greater risk. (Models: NEPA, CERCLA.)

(2) It would restrict release of pesticides when they are used. (Models: RCRA, CERCLA, CWA, CAA.)

(3) It would provide ecological and health-based standards in the media (air, water, soil) that trigger further restrictions on use. (Models: RCRA, CERCLA, CWA, CAA, SDWA.)

(4) It would accomplish the above through a thorough consideration of all alternative pest management strategies and all the costs and benefits of each, giving greater weight to public health and environmental costs/benefits than economic costs/benefits. The burden of proof would be reversed -- pesticides could be released only if there were substantial risks of not using them and the risks of use are not excessive. The burden would be on the manufacturer to show that a chemical solution is the best way to address the problem. (Models: NEPA, CERCLA.)

(5) The manufacturer and user would bear the burden of liability and recalls if uses were shown to be unsafe. (Models: CERCLA, RCRA, Consumer Product Safety Act.)

(6) Citizens would have the right to initiate enforcement action if enforcement agencies did not respond. (Models: CWA, CAA, RCRA.)

An Invitation to Congress

Those who have become accustomed to working within the constraints of FIFRA will require a greater understanding of other statutes. A prerequisite of real pesticide reform is a major change in world view among legislators. Legislators who have crafted toxics legislation that protects public health and the environment must recognize that the same standards of protection should apply for pesticides as for other toxics. They must recognize how FIFRA fails to meet those standards and how FIFRA's shortcomings cause unacceptable risks to public health and the environment.

On the other hand, those legislators on the Agriculture Committees who have traditionally handled pesticide legislation must recognize that we can manage pest problems without broadcasting toxins.

The Chlordane Experience: A Case In Point

NCAMP petitioned EPA on March 23, 1987, seeking an emergency suspension of the termite pesticides chlordane, heptachlor, aldrin and dieldrin. A perfect showcase for demonstration of the practical effect of the gaping holes which exist in S. 1516 can be seen in the context of the termiticide problem. These rank number one in NCAMP's records.

The S. 1516 package does not do nearly enough to protect either the American public or the environment, from pesticide hazards. It does not help our citizens when they are adversely affected by these poisons, and it has not been written to defend the public health by aggressively forbidding registration of untested, or even clearly hazardous, products.

Any homeowner knows that almost anywhere in the U.S., any time a house is bought and sold, mortgage lenders require that the house be certified termite-free. The National Pest Control Association estimated that 1.5 million termite treatments take place annually. The EPA estimates that 90% or more of these treatments are performed with chlordane, heptachlor or aldrin (all closely related to one another chemically). Retreatments within only a few years are common. However, as long ago as 1974, EPA identified these termiticides as "imminent hazards" to the public health, due to findings of carcinogenicity in animals and a tendency for residues to accumulate in the food chain and in human tissues. EPA banned all agricultural uses in 1978, after lengthy hearings.

S. 1516 Does Not Require Data Submission on Indoor Residues Left Behind When Pesticides Are Used in Homes

In the case of chlordane, EPA failed to investigate reports that air residues were polluting the nations homes at any time during Cancellation hearings held in the '70's. The phenomenon of rising public awareness and alarm that termiticides were indoor air polluters was what led EPA to take the unusual step of requiring "special" air-monitoring studies from the manufacturer, studies which now confirm that even when applied by industry-selected professionals, in industry-selected homes, according to label directions, carcinogenic termiticides pollute home air at unacceptably high levels! S. 1516 makes no attempt to force EPA to examine the question of indoor residues of pesticides.

S. 1516 Does Nothing to Upgrade the Current Deplorable Standards for Pesticide Applicator Certification and Training

Last year, EPA proposed to make chlordane and company "restricted use" pesticides, to be applied only by certified applicators. In fact, EPA exhibited incredible complacency, stating that the termiticide problem was solely one of misapplicaton and misuse, while omitting review either of available data on human exposure indoors, or the experience of states in which such a strategy had already been tried and failed. Certification is extremely easy to obtain, and is no guarantee that the applicator will know anything about the hazards of the pesticides employed. We hear over and over again from people who have been contaminated by certified applicators.

S. 1516 Retains Extremely Weak Enforcement Provisions

Chlordane in a bottle is a product, but in a contaminated house, everything it binds to becomes a hazardous waste, legally disposable only in secure landfills. Chlordane contamination victims can and do lose their homes, and all their belongings. Penalties, when imposed on an applicator, are generally small (a few thousand dollars), and out of all proportion to the financial damage inflicted on the victim.

S. 1516 Contains No Citizen Suit Provision

Chlordane contamination victims generally try to involve regulators, usually the Departments of Agriculture, in the investigation of torts committed by applicators, but are very often unsuccessful even in getting regulators to come out and take an air sample. These regulators, usually refer consumers to private laboratories, where air analysis for cyclodiene termiticides cost between $300-$1000. For "indemnification" of homes and belongings, regulatory agencies generally refer the unhappy homeowners to the mercy of the court system. What does it cost these days to prepare a chlordane case for trial? One lawyer told us that he spent $70,000, exclusive of his time. Most people, discouraged by the uncertain prospect of risking life savings, just give up. Those well-heeled, more risk-minded individuals, who hang in there live through years of anxiety waiting for resolution of their cases.

S. 1516 Retains Indemnification Provisions for Manufacturers of Products Suspended by EPA

Suffice it to say that, according to EPA, the annual budget for the Office of Pesticide Programs is $40 million, while preliminary estimates predict that it will cost $50-60 million to buy up just 6 months production of chlordane, alone, excluding carryover from any previous production, and the attendant storage, transportation, and disposal costs.

Legislative Proposal

In light of the situation described above, we would urge, at a minimum, the following:

Ensure that any bill that emerges out of the Committee does not contain the following provisions:

- preemption of state government authority to set more stringent food safety standards than the federal government;

- limits on farmer liability associated with contamination incidents;

- groundwater protection language with inadequate safety standards and little emphasis on prevention;

- "conditional," "minor use," and "special local need" loopholes that allow products to enter the marketplace or have their uses expanded despite the fact that there are established risks or incomplete health and safety data;

- inadequate resources to meet health and safety testing deadlines;

- dichotomy between dietary exposure or food use pesticides with other non-food use exposure or pesticides, thus subjecting those exposed to pesticides through the air to higher risks;

- slap-on-the-wrist penalties for violations of the law;

- inadequate pesticide applicator competency training;

- limited pesticide applicator record keeping requirement; and,

- simple reporting requirements for exportation of banned or highly restricted pesticides, as opposed to restrictions on shipping and product labelling and packaging.

Similarly, legislation that moves through the Committee and Congress should strengthen clear weaknesses in the existing law. In fact, with the partial exception of the indemnification provision, the legislation and amendments before the Committee leave in place unacceptable provisions in current law:

- requirement that EPA indemnify manufacturers affected by a pesticide suspension for monetary losses and payment for storage, transportation, and disposal of stocks;

- ineffective enforcement system lacking a citizen suit or private right of action provision, leaving citizens unable to bring lawsuits under the law for violation of the statute; and,

- no control of indoor air residues of pesticides.

Conclusion

Mr. Chairman and members of the Committee, we appreciate the your attention to the pesticide problem. We urge you to seek a comprehensive response that moves the nation forward, not backwards. Recognize that we cannot stand still, because that only allows the contamination and poisoning to continue unabated. For an organization like ours that is in contact with poisoning victims across the United State, it is painfully ironic to us that in the 25th anniversary year of Rachel Carson's Silent Spring, an effort to bring our national pesticide law up to the standards of other environmental laws remains desperately needed and still so controversial in this Committee. We look forward to working with you to construct an adequate response to the growing pesticide contamination problem.

National Coalition Against the Misuse of Pesticides
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October 16, 1987

The Honorable Patrick Leahy
Chairman
Committee on Agriculture,
Nutrition and Forestry
U.S. Senate
Washington, D.C. 20510

Dear Senator Leahy:

I apologize for the delay in responding to Senator Pryor's questions at the July 30th Senate Agriculture Committee hearings on reauthorization of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). As you may know, the National Coalition Against the Misuse of Pesticides (NCAMP) has put extensive time recently into litigation against the U.S. Environmental Protection Agency (EPA) on the matter of continued use of the carcinogenic termite insecticides chlordane and heptachlor. We have, in essence, over the last several months been trying our utmost to make FIFRA work, if you will. Our litigation serves as a shining example of how poorly the public is protected from toxic pesticides under this extremely weak and ineffective statute.

I would like to return to this matter of chlordane as a part of my response to the Committee's questions. It is only through specific experiences like this and others in which NCAMP has been involved that one can appreciate the lack of protection that FIFRA offers.

What is your top priority for FIFRA reform?

The top priority for FIFRA reform, as we see it, is a significant shift in the orientation of the act to provide for, and in effect facilitate, safe and efficacious pest management programs, while efficiently outlawing toxic materials that cause adverse human health and environmental effects. We recognize that this goal is currently outside the scope of what the committee and S. 1516 are addressing. However, we feel it is not sufficient to simply tinker with an outdated and fundamentally flawed licensing law like FIFRA, ignore basic questions of safety standards and product efficacy, attach a five (5) year reauthorization to the legislation, and label the effort "FIFRA reform." Unfortunately, this is exactly what is happening.

The centerpiece of S. 1516 is the reregistration of pesticides that have never been fully registered in conformance with the requirements of FIFRA. The goal is valid, but only in context. If the information generated under the reregistration program does not trigger acceptable regulatory responses, then there is virtually no purpose in carrying out the safety tests. EPA's response to chlordane serves as an example of safety data generation (or registration) not triggering a regulatory response. In effect, the Agency had found in the mid-1970's that chlordane posed an imminent hazard, given its potent carcinogenic properties. The material was regulated out of agricultural use, but its structural uses were retained pending the generation of exposure data. Over a decade later, EPA began responding to exposure data that it had available to it for several years. In effect, EPA began indicating, as a result of public pressure, that it was considering action. Despite evidence of human exposure following proper labeled application of the material and despite the fact that volatilization of the material into a home constitutes a threat to residents of treated homes for decades after legal application, EPA was not moved by any statutory standard of safety. As serious, when the Agency negotiated a deal with the registrant that allowed for continued human exposure, officials did not feel compelled by any provision of the law to provide a scientific explanation for its action and an analysis of why it was not pursuing other regulatory options.

As you know, EPA negotiatated a deal with the manufacturer of chlordane/heptachlor which left hundreds of thousands of gallons on the market to be used in at least 150,000 homes (a conservative estimate), while the existing stocks were being exhausted. EPA allowed this without any duty to the public to explain why it was not putting a cap on existing stocks, and why it was not stopping use immediately. The Agency acted without any accurate accounting of the actual volume of stocks in the hands of distributors and pest control operators, without any risk numbers on the people who would be adversely affected as a result of exposure to these supplies, and without any accurate accounting of the availability of alternative termiticides. EPA allowed continued use because, to paraphase EPA officials, "It was the best deal we could cut and our alternative under FIFRA would be lengthly cancellation proceedings that could last several years and eat up Agency resources and time." There was some talk that EPA did not want to pay a hefty indemnification payment associated with a suspension action, which the Assistant Administrator denied, but there was more talk that the Agency did not think the resource-intensive regulatory process, subject to administrative judicial review, was worth the cost.

FIFRA is too unwieldy to implement, so regulators may feel compelled to negotiate deals, inevitably allowing years of deadly pesticide supplies to be exhausted because the resource- and time-intensive regulatory process is too costly. EPA may be correct in believing that even when data is available showing the magnitude of risk associated with chlordane, the law does not require regulatory action, if in the judgement of the Agency the benefits may outweigh the risks.

The wide discretionary authority afforded the Administrator is untouched by legislation now on the table. Where is it required that the registrant or the Administrator must prove the benefits with solid field data? Where is it required that EPA collect efficacy data to show that insect resistance to chlordane or any other pesticide does not undermine the benefit assumptions? Where is it required that EPA scientifically collect misuse information and incorporate that information into a regulatory decision that finds a pesticide cannot be used safely? The current law and the legislation does not address any of these severe limitations that are responsible for vast numbers of poisonings and contaminations.

As a result, we are left with legislation that does not address the priority of the day: control pests with less or, in many cases, no pesticides. Grow less and reduce the commodity surplus problem as discussed in the attached article, which shows 110 million pounds of pesticides being used in 1986 to grow surplus wheat and corn for which there is no market. We must consider reorienting the statute to allow the registration of pesticides on the basis of essentiality, with a strict accounting of product efficacy at the time of registration and throughout its product life. We must reorient the statute to more clearly distinguish between the essential need for a pesticide and the cosmetic need and then regulate accordingly.

Because of the situation described here with chlordane and repeated time and time again with other pesticides, we have made the statement in the testimony delivered to this committee that S. 1516 is more notable for what it does not do than for what it does.

Is the overall S. 1516 legislation a net improvement over this year's House bill, H.R. 2463?

As we have stated in our testimony, H.R. 2363, plus amendments its sponsors have said they will introduce in committee, constitutes a setback overall. We have opposed that legislation because when we stack up preemption of state authority [to adopt stronger food safety standards] with inadequate funding to meet imposed deadlines for reevaluation of product safety, and add to it disincentives for EPA action to suspend and cancel deadly materials [requiring EPA to buy up stocks and finance disposal, and lengthly cancellation proceedings and challenges] with a whole set of additional provisions, the total package is a step backward rather than forward.

S. 1516, as legislation that tinkers with FIFRA problems such as indemnification and reregistration problems, does not eliminate the many disincentives for necessary regulatory outcomes, including restriction or cancellation of many pesticide products. Importantly, in addition to eliminating discentives to regulatory action, a reorientation toward the promotion of safe and effective pest management is critical.

Do you agree that overall S. 1516 is a net improvement over the current law?

The worst thing that this committee could do is to give the impression that S. 1516 will correct the underlying problems that are responsible for the rising tide of public concern about dangerous pesticides in the drinking water, food, schools, homes, parks and workplaces. At best, the bill could be characterized as an emergency measure that addresses reregistration (partially, because of a still inadequate revenue-generating fee provision) and indemnification (partially, because the Agriculture Committee could still approve indemnification payments). It does not change the thrust of the act or the orientation referred to above.

Insofar as S. 1516 addresses only a small part of the pesticide problem, NCAMP could not support any FIFRA reauthorization, short of a reform measure, with a five (5) year reauthorization. In fact, we could not support any legislation of this nature that did not bring with it a commitment from the chairman and its sponsors to revisit the larger reform issues immediately in the next session. Therefore, anything longer than a two (2) year reauthorization period is unacceptable from a public health and environmental protection perspective and will be opposed by this organization and others.

Thank you for the opportunity to respond to these questions. Our responses here are not meant to serve as a comprehensive discussion of the problem, which is contained in the prepared comments which we have submitted and wish to be included in the formal hearing record.

We look forward to working with you in an effort to develop an acceptable statutory response to one of the most troubling poisoning and contamination problems of our time.

Sincerely,

Jay Feldman
National Coordinator

encl.

6 Friday, March 27, 1987 The Washington Post

Farmers Idling Vast Acreage

Heavy Enrollment Reported in New Conservation Reserve Program

By Ward Sinclair
Washington Post Staff Writer

Government production controls and heavy enrollment in the new soil conservation reserve program will idle more than three of every 10 acres of farm land eligible for federal subsidies this year—the second highest level in history, according to the Agriculture Department.

The USDA estimates that farmers will retire 53 million acres as a requirement for participating in federal support programs and that another 19.4 million highly erodible acres will be in the long-term conservation reserve, keeping them out of production for 10 years.

The estimate of 72.4 million acres lying idle compares with the record 78 million acres in 1983, when the USDA paid farmers not to plant, and with 54.2 million acres held out of production last year.

A key difference this year is the massive enrollment in the conservation reserve, which attracted an additional 10.5 million acres during a February sign-up period, putting the program almost 5 million acres ahead of the schedule laid out by Congress when it created the reserve in 1985 farm legislation.

The reserve pays farmers a yearly fee for retiring their most erodible land for at least 10 years. The government also shares the cost of planting grass and trees to help prevent further erosion. Per-acre fees vary from state to state.

USDA officials and conservationists agree that interest increased after the department, in an effort to offset financial enticements of other federal support programs, offered corn farmers a bonus of $2 for every bushel they agreed not to grow by entering their most erodible land in the reserve.

The one-time-only bonus payments will cost the government slightly more than $340 million, still a saving over what might have been had farmers planted corn on those acres. Price-support loans and subsidy payments of $1.21 a bushel would have been considerably higher, USDA said.

"We would have been looking at payments of about $3 per bushel for the 1987 crop," said William C. Bailey, a deputy administrator of the Agricultural Stabilization and Conservation Service, which oversees farm-support programs. "You look at the $2 bonus versus the $3 benefit for the farmer, and you see that it obviously pays. There will be even larger savings in the out-years."

The appeal of the $2 bonus payments was evident in major Corn Belt states, where farmers last month enrolled far more acreage in the reserve than they had during past sign-up periods. Conservationists had argued that, without some kind of bonus, midwestern farmers would continue to find crop-support programs more attractive.

In Iowa, for example, slightly more than 1 million acres were enrolled in February, bringing farmers $122.7 million in bonuses, compared with 359,000 acres enrolled in sign-up periods last year.

Minnesotans, with $45 million in bonuses, put 889,850 acres in the reserve, compared with about 660,000 acres last year. Nebraska received $35 million in bonuses with 553,728 acres, compared with 298,234 last year.

Even with the massive land retirement, Bailey added, major surpluses of basic commodities are expected to keep holding down prices, particularly in corn and wheat.

In corn, for example, surplus stocks next October are expected to be about 5.9 billion bushels, enough to feed the country for 10 months or supply U.S. export needs for four years.

Corn surpluses have continued to grow despite USDA efforts to reduce output by requiring farmers to idle part of their land in return for receiving crop-support loans and direct income subsidies known as deficiency payments.

Surplus production, in addition to its price-depressing effects, has cost farmers in other ways, according to a Conservation Foundation report last year. It said surpluses "represent an elevated risk of environmental impacts from the extra use of nitrogen and phosphate fertilizers and of pesticides, especially herbicides and insecticides."

The foundation said U.S. corn and wheat farmers used more than 7.3 billion pounds of fertilizer and 110 million pounds of pesticides to grow crops for which there is no market in 1986.

"Those amounts are equivalent to about 28 percent of the fertilizer and 40 percent of the pesticides used on corn and wheat in 1986," foundation President William K. Reilly recently wrote in the Journal of Soil & Water Conservation.

Senator **Pryor**. Because of the lateness of the hour, I will not ask for answers to these questions orally at this time, but the committee would like to get your responses in writing to these three questions. Now when you answer, please do not write a book, but give us a succinct answer as to:

One, what is your top priority for FIFRA reform?

The second question is on the overall S. 1516 legislation. Is this a net improvement over this year's House bill, H.R. 2463?

Third, do you agree that overall, S. 1516 is a net improvement over the current law?

Please state your reasons why or why not. We would like those three questions answered. We respectfully submit those to the groups represented here and we are very indebted for your testimony this afternoon. Thank you.

[Editor's note.—The answers to Senator Pryor's three questions can be found on pages 307, 320, 327, 368, and 386.]

Senator **Pryor**. I think we have two panels. I am going to combine the final panel, ladies and gentlemen.

Mr. Mark Maslyn from the Farm Bureau; Claudia Fuquay from United Fresh Fruit and Vegetable Association; Mr. Lawrence T. Graham, National Food Processors; Mr. Bill Darrow, Green Mountain Orchards, Putney, Vermont; Mr. John F. Hall, president of the American Wood Preservers Institute, Vienna, Virginia. If this panel would take their seat.

Now, please pardon the personal reference, but I see one familiar face that I saw on Monday of this week in the State of Vermont. I believe you are the gentleman who—is this correct? Did you not rise from the audience and give a statement?

Mr. **Darrow**. It is nice to see you again, sir.

Senator **Pryor**. And I want to compliment you on your State. That was my first time to visit there, and it was an enjoyable day, and I think a very productive hearing. Mr. Maslyn, you will be our first witness. Thank you.

STATEMENT OF MARK A. MASLYN, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION, WASHINGTON, DC

Mr. **Maslyn**. Thank you, Senator. On behalf of the Farm Bureau, Federation, I appreciate the opportunity to be here today and share with you our concerns about the attempts in 1987 to reauthorize FIFRA.

Let me say at the outset that Farm Bureau hopes Congress will be able to reauthorize FIFRA. We recognize the need for changes. We participated extensively in negotiations and compromise efforts over the past 2 years. In our opinion, however, this bill does not reflect the spirit of compromise in last year's legislation effort. The provisions most central to agriculture's concern, addressing the issues of liability and uniform tolerances, have been summarily dropped from S. 1516. The Farm Bureau's continued support of FIFRA reauthorization efforts is contingent upon addressing these important issues.

We strongly agree with the need to expedite the reregistration of older pesticide products. At the same time, however, we have expressed reservations in the past about the use of user fees to accomplish this task which we believe to benefit society rather than a particular industry or segment of the economy. We did, however, accept the $150,000 fee, provided it was a one-time, single-purpose assessment that would not be increased or implemented again. S. 1516 proposes to quintuple many of these fees over a 5-year period. Without a doubt, the cost of this effort will be borne by farmers and ranchers as these fees are passed through to the end user. We would urge the committee to remain firm in opposition to the inevitable pressure to increase the amount or expand the use of these fees.

Another important issue presently omitted from this bill deals with the pesticides in ground water issue. We believe it is particularly appropriate that this committee address this issue in the context of FIFRA. We believe that the Durenberger-Leahy ground water amendment could be made more flexible and accommodate the needs of agriculture while still maintaining a strong preventive approach to ground water contamination.

Specifically, we are concerned about the broad definition of the resource area to be protected and the lack of any consideration of benefits of agricultural chemicals. We need to be concerned about pesticide contamination of ground water. But we must also recognize that contamination at the levels we can currently detect may not pose a threat. Simply put, we must be prepared to put the issue into perspective and discern the difference between the presence of a pesticide contaminant and the presence of a risk.

Related directly to the pesticides and ground water contamination issue is the question of liability. We are very troubled by the initial decision of the sponsors to avoid this important issue. The Farm Bureau has pushed actively for Congress to address this issue as it relates to the lawful application of pesticides registered by the Federal Government.

For many years now, we have advocated the position that if farmers use agricultural chemicals in compliance with federally approved label instructions, they should not be subject to liability for damages, for remedial relief, or the costs associated with such relief or cleanup. It is not only just plain fair to the producer, but it also makes good environmental sense. What better incentive could there be for a producer to take that extra measure of caution in the use of agricultural chemicals? We would hope that the committee could address this issue in a meaningful way during this review of FIFRA.

Finally, another issue in this debate, also omitted from this bill, is that of national uniformity. It is equally as important as the issue of liability. The original language has been extensively modified as a result of last year's negotiations. It is now entirely prospective. This provision actually establishes States rights in setting tolerances that do not exist in current law. The language establishes exceptions whereby the State, in the event of an imminent hazard, or if the State follows a petition process, may obtain a waiver that would allow it to set a different tolerance level. The uniform tolerance amendment would also permit States to establish more stringent tolerances if the pesticide did not have a complete data base. That does not strike me as being preemptive of States rights.

To the farmer, the issue is simple. It is one of uniformity and consistency. To the grower, whose raw and processed products are often marketed across State lines, varying tolerances from State to State would effectively end the use of certain chemical products and limit market opportunities. Such actions undoubtedly have had an adverse economic and management impact on farmers and impair their ability for long-term planning.

We urge the committee to include the uniform tolerance provision in S. 1516.

Senator **Pryor**. Mr. Masyln, are you at the conclusion of your statement?

Mr. **Maslyn**. On behalf of the Farm Bureau, I appreciate this chance to testify.

Senator **Pryor**. Thank you. Your entire statement will be entered in the record.

Mr. **Maslyn**. Thank you.

[The prepared statement of Mr. Maslyn follows:]

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STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION TO THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY WITH REGARD TO S. 1516 -- FIFRA

Presented by Mark A. Maslyn
Assistant Director, National Affairs Division

July 30, 1987

American Farm Bureau Federation
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STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION TO THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY WITH REGARD TO S. 1516 -- FIFRA

Presented by Mark A. Maslyn
Assistant Director, National Affairs Division

July 30, 1987

On behalf of the American Farm Bureau Federation, I appreciate the opportunity to be here today to share with you our concerns and comments on legislation to amend the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), S. 1516. The American Farm Bureau Federation is a general farm organization with more than 3.5 million member families in 49 states and Puerto Rico. The membership of Farm Bureau includes producers of nearly every crop grown and harvested commercially in the United States.

Let me say at the outset that Farm Bureau hopes Congress will be able to pass a multi-year FIFRA reauthorization in 1987. We recognize the need for changes to the Federal Insecticide, Fungicide and Rodenticide Act and have participated extensively in negotiations and compromise efforts over the past two years. In our opinion however, this bill does not reflect the spirit of compromise in last year's effort. The provisions most central to agriculture's concern addressing the issues of liability and uniform tolerances have been summarily dropped from S. 1516. Farm Bureau's continued support of FIFRA reauthorization efforts is contingent upon progress on these important issues.

In our review of S. 1516, we find many provisions with potentially significant impacts on agricultural producers. To illustrate this point, we need look no further than the issue of reregistrations believed by many to be the engine that is driving this bill. We strongly agree with the need to expedite the reregistration of older pesticide products. At the same time, we have expressed reservations in the past about the use of user fees to accomplish this task, which we believe to benefit society rather than a particular industry or segment of the economy. We have, however, accepted the $150,000 fee, provided it is a one-time, single-purpose assessment that would not be increased or implemented again. S. 1516 proposes to quintuple many of these fees over a five-year period. Without a doubt, the cost of this effort will be borne by farmers and ranchers as these fees are passed on to the end user. We would urge the Committee to remain firm in opposition to the inevitable pressure to increase the amount or expand the use of these fees.

Beyond the issue of fees, the impact of the reregistration process on agricultural producers will come if registrants balk at the potentially multi-million dollar expense of filling data gaps and the registrations are then subsequently cancelled. The effect could be particularly acute for producers of specialty or so-called minor crops. We will pay close attention to this as the process of reregistration moves forward. Nevertheless, we believe the objective of reregistration is in farmers' interest and should be completed as expeditiously as possible.

Another important issue presently omitted from this bill deals with pesticides in groundwater. We believe it is particularly appropriate for this Committee to address this issue in the context of FIFRA. From an agricultural and rural perspective, groundwater is a vital natural resource, and its potential contamination poses very serious and unique problems to farmers. Over 90 percent of our rural population relies on groundwater as a source of drinking water. This is complicated by the fact that agricultural pesticides have been cited as sources of groundwater contamination. Farmers are thus faced with a dilemma between the need to ensure that millions of private wells in our rural areas remain a safe source of drinking water, and the need to ensure that in achieving that end, we do not make farming and ranching an unprofitable or impractical venture. We believe that the Durenberger/Leahy groundwater amendment could be made more flexible and accommodate the needs of agriculture while still maintaining a strong preventive approach to groundwater contamination.

Specifically we are concerned about the broad definition of the resource area to be protected and the lack of any consideration of benefits of agricultural chemicals. We need to be concerned about pesticide contamination of groundwater. But we must also recognize that contamination at the levels we can currently detect may not pose a threat. Simply put, we must be prepared to put the issue into perspective and discern the difference between the presence of a contaminant and the presence of a risk.

Related directly to the pesticides and groundwater issue is the question of liability. We are very troubled by the initial decision of the sponsors to avoid this important issue. Farm Bureau has pushed actively for Congress to address this issue as it relates to the lawful application of pesticides registered by the federal government. It is an extremely complicated issue to address, fraught with many subtleties and nuances, but one that inevitably will have to be dealt with. The congressional debate over pesticides in groundwater, the agricultural chemicals groundwater strategy being developed by EPA and the nationwide well sampling program being conducted by EPA all point to the urgent need to delineate a clear and consistent federal policy in this area.

For many years now, the we have advocated the position that if farmers use agricultural chemicals in compliance with federally approved label instructions, they should not be subject to liability for damages, for remedial relief, or the costs associated with such relief or cleanup. It is not only just plain fair to the producer, but it also makes good environmental sense. What better incentive could there be for a producer to take that extra measure of caution in the use of agricultural chemicals? This concept is important to farmers and ranchers and we hope that the Committee will reaffirm its support for an effective liability protection provision.

Finally, another issue in this debate, also omitted from this bill, is that of national uniformity. It is equally as important as the issue of liability. The original language has been extensively modified as a result of last year's efforts, and is now entirely prospective. As contained in H.R. 2463 it applies only to those chemicals registered or reregistered after 1985 that meet all current EPA data requirements. This provision actually establishes states rights in the tolerance setting process that do not exist in current law! Furthermore, the language establishes exceptions whereby the state, in the event of an imminent hazard or if the state follows a petition process, may obtain a waiver that would allow it to set a different tolerance level. The uniform tolerance amendment would also permit states to establish more stringent tolerances if the pesticide did not have a complete data base. That does not strike me as being preemptive of states rights.

To the farmer, the issue is simple. It's one of uniformity and consistency. To the grower, whose raw and processed products are often marketed across state lines, varying tolerances from state to state would effectively end the use of certain chemical products and limit market opportunities. Such actions undoubtedly have had an adverse economic and management impact on farmers and impair their ability for long-term planning.

We therefore urge the Committee to include the uniform tolerance amendment to S. 1516.

In conclusion, we believe the bill before us today falls well short of a compromise that farmers and ranchers could support. From the producer's standpoint, the important issues remain outstanding. It is our hope that before the process ends this bill will indeed address these issues and truly be a balanced compromise effort.

On behalf of the Farm Bureau, I appreciate the opportunity to appear here today and would be happy to answer any questions you may have on these or other provisions of this bill. Thank you.

Senator **Pryor**. Claudia Fuquay, and you are with the United Fresh Fruit and Vegetable Association. We welcome your testimony.

STATEMENT OF CLAUDIA R. FUQUAY, DIRECTOR OF CONGRESSIONAL RELATIONS, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Ms. **Fuquay**. Thank you, Mr. Chairman. United Fresh Fruit and Vegetable Association is the national trade association for the fresh produce industry. United's members handle over 80 percent of the fresh produce commercially marketed in the United States. As agricultural users, our members recognize the need for changes to FIFRA.

United supports the basic impetus for this legislation, to accelerate the reregistration process and to close the data gaps in order to ensure the safety of the pesticides we use.

Of major concern to our industry, however, is the continued availability of safe and effective agrichemicals as the EPA pursues a more expeditious reregistration program. Because chemical manufacturers are now faced with the more stringent data requirements enacted in 1978, many of these manufacturers have already started to voluntarily cancel older chemicals that have proven effective for our industry. For the most part, the decision to cancel is not based on health concerns but for economic reasons. If appropriate action is not taken quickly, we are concerned that there will be fewer registrations of pesticides solely for use on fruits and vegetables which are considered minor crops for pesticide use.

We commend the sponsors of this bill for the recognition they have given to the minor use and minor crop problems. However, we believe such considerations must go even further. Our industry is not recommending that we lessen the safety and health considerations for pesticide use on minor crops, which includes all fruits and vegetables. In fact, just the opposite is true. We believe in furnishing the safest product possible. We do feel that the producers of these crops have unique needs and that incentives should be provided to the manufacturer and other parties that register a pesticide for a minor use.

First, title III, section 301 of S. 1516 directs the Administrator to set priorities for the reregistration of pesticides and in doing so to consider the pesticide a high priority if it would be used on crops where worker exposure is most likely to occur. Since fruits and vegetables are labor intensive crops, all pesticides for this use would come under early scrutiny during the reregistration process. For economic reasons, we expect that manufacturers will voluntarily cancel many registrations of these older chemicals. We urge Congress to require EPA to give a high priority to registrations of new pesticides for use on fruits and vegetables. Without such an incentive, the industry believes that a number of pesticides will be removed from the market and that no replacements will be available.

Second, the Senate provision for reregistration fees is drastically different from the fee structure agreed to in the 99th Congress and contained in the House bill [H.R. 2463]. The House bill provides for a one time maximum fee of $150,000. This bill requires a fee of $150,000 annually for 5 years to reregister an active ingredient contained in pesticides that collectively generate annual gross revenue for the registrants of $10 million or more. If the collective annual gross revenue is less than $10 million, the fee is $20,000 a year for 5 years, a total of $100,000. The Senate fee structure does not give the Administrator the choice of waiving the fee in case of reregistrations for pesticides to be used on minor crops.

Although many pesticides used solely on fruits and vegetables would qualify for the lower fee of $20,000 annually, we are concerned that the manufacturers would simply decide to cancel these older chemicals. A reregistration fee of $100,000 for a pesticide with minimal economic return is rather costly.

The House bill does allow for waiver of the reregistration fee if the chemical is registered solely for a minor use. United recommends that this committee reinstate the waiver of fees for minor crops.

Among our members are a large number of growers who depend on accurate label information. United strongly believes that application of a pesticide in accordance with the label should preclude the agricultural producer from liability. We would be pleased to work on specific language with the committee staff. The question of liability is increasingly of great concern to our members. We urge this committee to take the necessary action to help alleviate such concerns.

Last year United cooperated with the EPA to develop new regulations that would protect the Nation's farmworkers from possible pesticide contamination. We understand that EPA will be transmitting draft regulations to Congress sometime this summer. Since EPA already has the authority to promulgate regulations, specific statute language is unnecessary. In fact, statutory language could be interpreted to mean that EPA must start from the beginning in the development of regulations in this area. For these reasons, we suggest that section 2003, "Worker Health and Safety," be deleted from S. 1516.

United would like to voice its support for a provision, "Uniformity in Tolerances and Food Additive Regulations," that was part of the amendments to FIFRA agreed to by this committee last year and which passed the House last year, but which is not a part of S. 1516. We believe that States should be required to follow strict Federal guidelines when setting residue tolerances different from those set by EPA. It is the EPA that reviews the required safety data and has the necessary expertise for setting tolerances. Without this uniformity, severe disruption of interstate commerce could occur.

We support the concept of last year's uniformity amendment, which for the first time, establishes a procedure by which a State may petition the Administrator for the authority to establish a State pesticide residue limit more stringent than the one set by the Federal Government.

Senator **Pryor**. Ms. Fuquay, pardon me. Are you reaching the end?

Ms. **Fuquay**. I am very close, yes.

Senator **Pryor**. Thank you.

Ms. **Fuquay**. Any such provision should also require that the petition be supported by scientific data.

Before concluding I would like to comment briefly on the ground water bill, S. 1419.

Our grower members are concerned about the contamination of ground water with pesticides. However, we must be realistic or American agriculture will lose the necessary tools for producing the abundant harvests of agricultural commodities.

S. 1419 equates current drinking water with potential sources of drinking water and requires action to reduce pesticide concentrations. We do not agree that there should be more stringent protection of private wells and potential drinking water than public drinking water systems, particularly when it would result in the banning of many agricultural chemicals.

United and its members oppose S. 1419. However, we would be willing to discuss alternative language and are reviewing the language in the House bill at this time.

I thank you for the opportunity to testify.

Senator **Pryor**. Thank you very much for your statement, Ms. Fuquay.

Ms. **Fuquay**. Thank you.

[The prepared statement of Ms. Fuquay follows:]

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Testimony

of the

United Fresh Fruit and Vegetable Association

before the

Committee on Agriculture, Nutrition and Forestry
United States Senate

on

Amendments to the
Federal Insecticide, Fungicide and Rodenticide Act
S. 1516

July 30, 1987

Mr. Chairman and members of the subcommittee, my name is Claudia R. Fuquay. I am Director of Congressional Relations for the United Fresh Fruit and Vegetable Association. United is the national trade association for the fresh produce industry. United's members handle over 80 percent of the fresh produce commercially marketed in the United States. We commend the Chairman for continuing the process to amend FIFRA in the 100th Congress. United's members as agricultural users recognize the need for changes to this law. We look forward to working with you on these issues as Congress fashions legislation that will meet the needs of the agricultural community, chemical manufacturers, and at the same time, protect consumers and the environment.

United supports the basic impetus for this legislation, to accelerate the reregistration process and to close the data gaps in order to ensure the safety of the pesticides we use.

Of major concern to our industry, however, is the continued availability of safe and effective agrichemicals as the EPA pursues a more expeditious reregistration program. Because chemical manufacturers are now faced with the more stringent data requirements enacted in 1978, many of these manufacturers have already started to voluntarily cancel older chemicals that have proven effective for our industry. For the most part, the decision to cancel is not based on health concerns but for economic reasons. If appropriate action is not taken quickly, we are concerned that there will be fewer registrations of pesticides solely for use on fruits and vegetables.

We commend the sponsors of this bill for the recognition they have given to the minor use and minor crop problems. However, we believe such considerations must go even further. Our industry is not recommending that we lessen the safety and health considerations for pesticide use on minor crops, which includes all fruits and vegetables. In fact, just the opposite is true. We believe in furnishing the safest product possible. We do feel that the producers of these crops have unique needs and that incentives should be provided to the manufacturer and other parties that register a pesticide for a minor use.

First, Title III, Section 301 of S. 1516 directs the Administrator to set priorities for the reregistration of pesticides and in doing so to consider the pesticide a high priority if it would be used on crops where "worker exposure is most likely to occur". Since fruits and vegetables are labor intensive crops, all pesticides for this use would come under early scrutiny during the reregistration process. For economic reasons we expect that manufacturers will voluntarily cancel many registrations of these older chemicals that are currently used solely on minor crops. We urge Congress to require EPA to give a high priority to registrations of new pesticides for use on fruits and vegetables. Without such an incentive, the industry believes that a number of pesticides will be removed from the market and that no replacements will be available.

Second, the Senate provision for reregistration fees is drastically different from the fee structure agreed to in the 99th Congress and contained in the current House bill (H.R. 2463). The House bill provides for a one time maximum fee of $150,000. This bill requires a fee of $150,000 annually for five years to reregister an active ingredient contained in pesticides that collectively generate annual gross revenue for the registrants of $10,000,000 or more. If the collective annual gross revenue is less than $10,000,000, the fee is $20,000 a year for five years, a total of $100,000. The Senate fee structure does not give the Administrator the choice of waiving the fee in the case of reregistrations for pesticides to be used on minor crops.

Although many pesticides used solely on fruits and vegetables would qualify for the lower fee of $20,000 annually, we are concerned that the manufacturers would simply decide to cancel these older chemicals. A reregistration fee of $100,000 for a pesticide with minimal economic return is rather costly.

The House bill does allow for a waiver of the reregistration fee if the chemical is registered solely for a minor use. United recommends that this committee reinstate the waiver of fees for minor crops. In fact, we would prefer that the waiver not be left to the discretion of the Administrator but would be automatic. The Agency has stated in its "Policy Statement on Minor Uses of Pesticides" that, "It is in the public interest to waive tolerance petition fees for pesticide minor uses that lack commercial feasibility to the pesticide industry". We believe that the waiver of the reregistration fees would be consistent with EPA's stated policy.

Third, the Interregional Research Project Number 4 (IR-4 Project) is responsible for establishing national priorities and developing data for pesticide minor uses in the public interest. This bill would amend 7 U.S.C. 450(i)(c) by adding a new sentence: "The Secretary in making grants...shall provide support for the interregional project number 4 program..." United and its membership appreciates the recognitio of the importance of the IR-4 Project and support this provision of the bill.

Among our members are a large number of growers who depend on accurate label information. United strongly believes that application of a pesticide in accordance with the label should preclude the agricultural producer from liability. We would be pleased to work on specific language with the committee staff. The question of liability is increasingly of great concern to our members. We urge this committee to take the necessary action to help alleviate such concerns. The Association strongly believes that if growers knowingly misuse a product then they should be punished. For this reason we support the penalty section included in S. 1516 and H.R. 2463.

Last year United cooperated with the EPA to develop new regulations that would protect the nation's farm workers from possible pesticide contamination. We understand that EPA will be transmitting draft regulations to Congress sometime this summer. Since EPA already has the authority to promulgate regulations, specific statute language is unnecessary. In fact, statutory language could be interpreted to mean that EPA must start from the beginning in the development of regulations in this area. For these reasons, we suggest that Section 2003, "Worker Health and Safety", be deleted from S. 1516.

United would like to voice its support for a provision, "Uniformity in Tolerances and Food Additive Regulations", that was part of the amendments to FIFRA agreed to by this committee last year and which passed the House last year, but is not a part of S. 1516. Current FIFRA law does prohibit states from imposing state pesticide labeling or packaging requirements different from those required under FIFRA. And, we believe that states should be required to follow strict federal guidelines when setting residue tolerances different from those set by EPA. It is the EPA that reviews the required safety data and has the necessary expertise for setting tolerances. Without this uniformity, severe disruption of interstate commerce could occur.

We support the concept of last year's uniformity amendment, which for the first time, establishes a procedure by which a state may petition the Administrator for the authority to establish a state pesticide residue limit more stringent than the one set by the federal government. Any such provision should also require that the petition be supported by scientific data.

We also request an amendment to Section 24(a) of FIFRA to prohibit the states from denying a registration simply because there is another pesticide already registered for use on the same crop for the same pest. Currently FIFRA prohibits the EPA from denying a registration simply because another product is available. We believe this prohibition should include the states since it is critical that the produce industry has an assortment of pesticides available to combat a wide range and ever increasing number of insects.

Before concluding, I would like to comment briefly on the groundwater bill (S.1419) cosponsored by Senators Leahy, Durenberger and others. United and its members question the impact this bill will have on agriculture.

Our grower members are concerned about the contamination of groundwater with pesticides. However, we must be realistic or American agriculture will lose the necessary tools for producing the abundant harvests of agricultural commodities.

S. 1419 equates current drinking water with potential sources of drinking water and requires action to reduce pesticide concentrations. We do not agree that there should be more stringent protection of private wells and potential drinking water than public water systems, particularly when it would result in the banning of many agricultural chemicals. Let me point out that these chemicals would be banned even if there are no alternatives.

United and its members oppose S. 1419. However, we would be willing to discuss alternative language such as contained in the House bill (H.R. 2463) that would protect our groundwater resources without a massive banning of pesticides currently in use by agriculture.

In conclusion, I would like to once again express United's support for acceleration of the reregistration process. However, the agricultural community has concerns that should also be addressed and United looks forward to working with the committee on these important issues.

I would like to thank you for this opportunity to testify and would be pleased to respond to any questions.

United Fresh Fruit and
Vegetable Association

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the fresh approach

August 6, 1987

The Honorable Patrick J. Leahy
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The United Fresh Fruit and Vegetable Association testified at the July 30 hearings on proposed amendments to FIFRA. During the morning session you asked EPA's witness, Jack Moore, whether or not he thought current FIFRA law provided the EPA with the necessary authority to waive reregistration fees as proposed in S. 1516. Dr. Moore responded that yes he felt EPA was provided that authority by Sec. 25 (b) of the current statute.

At the afternoon session of the hearings, the United and other agricultural witnesses were requested to respond in writing whether or not we believed current FIFRA law already provided the authority for the waiving of reregistration fees. Please consider this letter as our official response to that question.

After the first reading of Sec. 25 (b), it would appear that this section does provide EPA the authority to waive the fees if the Administrator determines the pesticide "to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act." However, since current FIFRA law does not contain a provision establishing reregistration fees, we are concerned that at some future date it could be argued that Sec. 25 (b) could not be considered as establishing the authority to waive fees.

United strongly urges that you add the authority to waive fees for minor uses to the current fee section of S. 1516.

If you would like to discuss this further, please do not hesitate to give me a call.

Sincerely,

Claudia R. Fuquay

Claudia R. Fuquay
Director, Congressional Relations

CRF/kln

cc: Committee on Agriculture, Nutrition and Forestry

Senator **Pryor**. Mr. Lawrence T. Graham. You are with the Food Processors.

STATEMENT OF LAWRENCE T. GRAHAM, EXECUTIVE VICE PRESIDENT, NATIONAL FOOD PROCESSORS ASSOCIATION, WASHINGTON, DC

Mr. **Graham**. Yes, thank you. I appreciate the opportunity, Mr. Chairman, to appear here today.

NFPA represents about 600 member companies nationwide that pack processed-prepared fruits, vegetables, meats, fish and specialty products. I am sure you would not object, Mr. Chairman, if I just summarize my statement here today, and I will try not to repeat some of the points already made that we are already in agreement with.

Senator **Pryor**. Thank you.

Mr. **Graham**. We are the association that packs food, processed and prepared food. So it is very important to us that we have high quality agricultural products available. For this reason, of course, we are very interested in FIFRA and support the reauthorization of FIFRA. We commend last year's efforts by this committee to amend FIFRA, and the bill before us now essentially reflects last year's attempt to reach some reasonable compromise.

We support the provisions in the bill to facilitate the pesticide reregistration process. We are pleased with certain provisions in the bill on minor use pesticides. The term minor use for our members is sort of a misnomer because it is a major use. Those pesticides are used on the majority of fruits and vegetables that our members pack and process and sell, of course, as retail products. Special considerations given these chemicals in regard to procedures for conditional registration and in the IR-4 program, for example, helps ensure their future availability.

However, we are concerned that S. 1516 fails to include a provision from last year's compromise package giving the Administrator of EPA the discretion to waive reregistration fees for minor use pesticides. The general effect of the reregistration fee schedule would be to make the reregistration of minor use pesticides more expensive and less attractive to the producers. Therefore, NFPA supports the inclusion of the discretionary fee waiver provision.

There are other amendments key to our industry support for the bill. I would say, without going over those in detail, the most important to us would be the national uniformity standard.

We strongly support the inclusion of this language to facilitate the interstate marketing of food and food products as reflected in the compromise bill of last year. As you are aware, the States would still be able to petition EPA for more stringent tolerances within that State.

And there are other provisions in the amendment that protect the State rights in this issue. Almost all of our members grow, process, market food products on a multistate or a national basis. Multiple inconsistent State pesticide tolerance levels frustrate EPA's attempts to set national standards and, important to our industry, they disrupt interstate commerce.

The uniformity amendment would meet our marketing needs and protect the public health equally in all 50 States. And as I mentioned, even with this national uniformity amendment, the States still play an important role in the setting of new tolerances. This national uniformity amendment is not just convenient for our members, but it is essential to the interstate marketing of our food and food products.

That essentially is a short summary, Mr. Chairman, of my prepared statement and I appreciate being able to appear here today.

Senator **Pryor**. I want to thank you, Mr. Graham, and I will have a question. I think for the record if you would answer this question.

Mr. **Graham**. Sure.

Senator **Pryor**. Or confirm or deny this. EPA testified that section 25(b) in FIFRA provides adequate authority to waive the fees; is this correct or not correct? Do we know?

Ms. **Fuquay**. It is correct that EPA made that comment. We reviewed the act today after EPA had made such a comment, and it does appear that it could give them that authority. But we would like to have somebody else look at it as well.

Senator **Pryor**. Right. You may submit your findings or thoughts for the record, and thank you very, very much.

Mr. **Graham**. We will do that.

[The prepared statement of Mr. Graham follows:]

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202/639-5900

STATEMENT OF THE
NATIONAL FOOD PROCESSORS ASSOCIATION
BEFORE THE
SENATE COMMITTEE ON AGRICULTURE
ON AMENDMENTS TO THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

S. 1516

JULY 30, 1987

Lawrence T. Graham
Executive Vice President

Statement of the
National Food Processors Association
Before the
Senate Committee on Agriculture
On Amendments to the
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
S. 1516
July 30, 1987

Mr. Chairman and members of the Committee, my name is Lawrence T. Graham. I am Executive Vice President for the National Food Processors Association (NFPA). I am accompanied today by H. Edward Dunkelberger, Jr. of Covington & Burling, counsel for NFPA. We appreciate this opportunity to present testimony today on amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

NFPA represents about 600 member companies nationwide that pack processed-prepared fruits, vegetables, meats, fish and specialty products. Also included among the association's members are companies that provide equipment, supplies and services to the food processing industry. NFPA operates three food research laboratories with over 100 employees conducting studies on food safety, nutrients and innovative technologies. The association's professional staff has extensive experience in food processing and pesticide residue analysis.

It is very important to our members that they have an abundant selection of safe, high quality raw agricultural products for the production of a wide variety of economical and nutritious foods. For this reason, FIFRA and the Federal Food, Drug, and Cosmetic Act are critical to the food processing industry.

NFPA commends last year's efforts by this committee to amend FIFRA. The bill before us now, S. 1516, essentially reflects last year's final attempt to reach a reasonable compromise between all concerned parties.

NFPA supports provisions in the bill to accelerate the pesticide reregistration process. Public confidence in EPA, and in the nation's food supply, will be greatly enhanced when this process is completed. By giving priority to active ingredients used on or in food, this goal will soon be realized.

We are pleased with certain provisions in S. 1516 for minor use pesticides. Minor use is a misnomer for this class of pesticides since they are critical for the production of a tremendous variety of fruits and vegetables which our members process. The special consideration given these chemicals in regard to procedures for conditional registration and the authorization of the Inter-Regional Project No. 4 (IR-4), will help ensure their future availability.

However, we are concerned that S. 1516 fails to include a provision from last year's compromise package giving the Administrator of EPA the discretion to waive reregistration fees for minor use pesticides. The general effect of the reregistration fee schedule of S. 1516, which requires pesticide producers to pay fees of $100,000 for pre-1978 active ingredients or $50,000 for post-1978 active ingredients, would be to make the reregistration of minor use pesticides more expensive and less attractive to the producers. Profits from minor use pesticides simply are not high enough to justify paying such fees. Therefore, NFPA supports inclusion of a discretionary fee waiver provision. In addition to these provisions NFPA would like to request that the committee look into further actions to help promote the research and development of pesticides for minor uses.

Other amendments key to our industry's support for a bill this year are also missing, namely, national uniformity of pesticide residue tolerances and limitation of liability for environmental damage from pesticide use.

On the liability issue, NFPA supports the inclusion of language to protect farmers from being held liable for environmental damages caused by pesticides. If a farmer applies the pesticide in accordance with all label instructions and does not act recklessly or negligently, he should not be held responsible for cleanup or other costs of environmental damage.

Perhaps the most critical issue for our members is national uniformity of pesticide residue tolerances. We strongly support inclusion of this language to facilitate interstate marketing of food and food products as reflected in the compromise bill of last year. This amendment would provide for a system of uniform tolerances for pesticides registered or reregistered after April 24, 1985, if EPA determines, after a public comment period, that the proposed tolerances protect human health, including the health of identifiable population groups with special food consumption patterns. However, a state would still be able to petition EPA for a more stringent tolerance within that state if scientific data reasonably raises concerns about the effect of a pesticide on human health and new data generated since the uniform tolerance took effect shows that the uniformity decision is unsupportable. EPA would have 180 days in which to rule on the petition. A petition could be denied only if the EPA finds that the uniform residue level protects human health, including the health of identifiable population groups with special food consumption patterns. The same procedures would apply to action levels for residues below which the FDA will not take enforcement action under the Federal Food, Drug, and Cosmetic Act.

The amendment also contains an important pipeline provision, which NFPA supports. Under that provision, where a state issues a new pesticide residue tolerance, food produced under the old tolerance would remain legal unless the state could prove that food produced under the old tolerance presents an unreasonable risk to human health. EPA and the USDA would have to consider feasible actions to minimize the time during which distribution of existing stocks meeting the old tolerance levels would occur.

Virtually all of our members grow, process and market their food products on a multi-state or national basis. Multiple inconsistent state pesticide tolerance levels frustrate EPA's attempts to set national standards and disrupt interstate commerce. The uniformity amendment would meet our marketing needs and protect the public health equally in all 50 states. Even with this national uniformity amendment the states would still play an important role in the setting of new tolerances and the changing of old ones.

Finally, NFPA supports inclusion of the groundwater protection provisions of last October's House passed bill. The quality of groundwater is of utmost concern to food processors. It is a vital resource in agricultural production from the farm through final processing operations. NFPA objects to the groundwater provisions included in S. 1419, however, for several reasons. First of all, S. 1419 considers all groundwater to be potential drinking water that should meet the same health-based standards. Some groundwater sources simply will never be used for drinking water due to saline or other factors. Also, the high monitoring costs imposed on pesticide producers by the requirements of S. 1419 will surely be passed on to agricultural producers, increasing the cost of food products. Finally, the standards of S. 1419 are needlessly stringent by requiring action when 50 percent of a Groundwater Residue Guidance Level (GRGL) is reached in a groundwater source. The GRGL is set by the bill at the Maximum Contaminant Level Goal (MCLG) of the Safe Drinking Water Act. MCLG's are very low standards, in some cases set at zero detectability. A trigger of 50 percent of this level is unwarranted. The language of last year's compromise on groundwater prevents contamination of sources and protects the public by use of reasonable standards. NFPA encourages the committee to adopt this plan.

Mr. Chairman, that concludes my testimony. I will try to answer any questions you may have.

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December 18, 1987

BY HAND

The Honorable Patrick J. Leahy
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is on behalf of the National Food Processors Association (NFPA) and in connection with the July 30, 1987 hearings on S.1516, proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). As you know, NFPA testified on July 30 in support of acceleration of the pesticide reregistration process, but urged that S.1516 be amended to include a provision giving the EPA Administrator discretion to waive reregistration fees for minor use pesticides.

It is our understanding that the EPA witness at the July 30 hearing, Dr. Jack Moore, testified that EPA has adequate existing authority to waive reregistration fees under Section 25(b) of FIFRA. This is in response to your request for NFPA's view as to whether Section 25(b) contains adequate authority to waive reregistration fees.

While NFPA supports Dr. Moore's interpretation of Section 25(b), and believes it to be a reasonable interpretation, NFPA is concerned that Dr. Moore's position may be challenged by persons opposing the waiver of reregistration fees, or may not be followed by subsequent EPA administrations. Because FIFRA does not currently provide for reregistration fees, it may be argued that Section 25(b) was not intended to provide EPA authority to waive such fees. To remove any ambiguity with respect to EPA's current authority, we urge that S.1516 be amended to grant EPA explicit power to waive reregistration fees.

We thank you for the opportunity to express for the record NFPA's views on this issue.

Sincerely,

Clausen Ely

Clausen Ely, Jr.

Senator **Pryor**. Mr. Bill Darrow from Putney, Vermont. We look forward to your statement, Mr. Darrow.

STATEMENT OF WILLIAM H. DARROW, JR., SENIOR MEMBER, GREEN MOUNTAIN ORCHARDS, PUTNEY, VT

Mr. **Darrow**. Sir, after all this discouraging talk about chemicals and pesticides today, I just feel happy to be alive and be here because I have been using them for 50 years, and I just feel fine.

You finally got a farmer and a pesticide user to testify. I am the senior member of Green Mountain Orchards, the largest family owned and operated apple orchard in Vermont. That does not mean it is very big because Vermont is a small State.

I am a serious environmentalist, second-generation apple grower who grew up on the farm. I know a bit about apple growing because I served as president of the Vermont Horticultural Society, president of the New York and New England Apple Institute, and the president of the National Apple Grower's Association, and as past Commissioner of Agriculture for the State of Vermont.

Vermont apple growers have a superb record of responsible chemical use. I touched lightly the other day on integrated pest management.[1] It has not been mentioned today. We do a lot of insect trapping in the orchard. We establish a minimum concentration of spray needed. We examine pest counts and see if we can get by with no spray at all.

The majority of New England apples are grown within the Integrated Pest Management [IPM] program. We respect the chemicals we use, and we use as little as we can. There is no incentive to use more than absolutely necessary. Sprays are expensive to purchase and expensive to apply. These high costs serve as a deterrent to the excessive use of sprays.

Fruit growers in spite of what you have heard here today have a superb record of good health. As I mentioned in Winooski,[1] I have been spraying every year since 1937. I have literally handled thousands and thousands of packages of chemicals and opened them with my own hands. I can see no negative effect, nor can my doctor, in the health of the four generations on our farm.

I grew up in the house that my children live in now, and some of my grandchildren are now living there. Our home is surrounded by apple trees that we spray only as needed for pest control, and you seem to be listening to a walking-talking healthy denial of some of the remarks here that have taken place today.

The big C, cancer, has everyone scared. We hear a lot of talk about carcinogens. Everyone seems to feel that pesticides are causing cancer. Just take note of a sample of apple growers involved, look them over, they have been using chemicals 10, 20, 30, 40, 50 years, and there is absolutely no evidence that they are more cancer prone than the general population. In fact, the opposite seems to be true.

In summary, one, Vermont apple growers are all environmentalists. We are a genuine mix of serious environmentalists and yet pesticide users.

---

[1] Mr. Darrow's remark is in reference to the hearing held on July 27, 1987, Winooski, Vermont, on Rural Agricultural Issues in the State of Vermont.

Second, two, three, and four generations are common on our farms. Last month we visited the Hardy farms in New Hampshire. Mr. Hardy, Sr. had just retired in March at age 100. My apple growing neighbor, Dwight Miller, is the seventh generation.

Three, as farmers, we need certainty for marketing. The 1987 national apple crop is the largest on record. We are very, very concerned about our ability to market it successfully because 99 percent of our apples are sold out of State. Since the 1986 crop was shipped to 16 different States, we need national pesticide standards.

Four, the apple growers of Vermont, of New England and New York, and the national apple growers, all request one national standard.

Five, on July 16, 1987, at the Massachusetts Fruit Growers annual summer meeting, I was asked by growers from Connecticut, Massachusetts, Maine, New Hampshire, and Vermont, how can we convince Pat Leahy that we need national standards?

Please, Mr. Chairman, consider these facts, and help us obtain a national standard. Thank you, sir.

Senator **Harkin** [presiding]. Thank you very much, Mr. Darrow.

[The prepared statement of Mr. Darrow follows:]

GMA

INTRODUCTION OF
MR. WILLIAM DARROW, JR., SENIOR MEMBER
GREEN MOUNTAIN ORCHARDS
TO THE
SENATE AGRICULTURE COMMITTEE
JULY 30, 1987

Mr. Chairman, thank you for inviting the Grocery Manufacturers of America (GMA), Inc. to present testimony on S. 1516, your legislation to amend the Federal Insecticide, Fungicide and Rodenticide Act.

My name is George W. Koch. I am GMA's President and Chief Executive Officer. GMA is an 80 year old national trade association, compromised of more than 130 companies which manufacture approximately 85 percent of the grocery products sold in retail stores throughout the United States. It is my honor to re-introduce to the Committee Mr. William Darrow of Putney, Vermont, an apple farmer and distinguished former Vermont Secretary of Agriculture. Mr. Darrow shares the views of more than 50 other farm organizations and GMA concerning the vital need to establish a system of uniform national tolerances covering only those chemicals which today pass every health test established by the federal government.

We would like to yield the balance of our time to Mr. Darrow who has a brief statement for the Committee.

Thank you Mr. Chairman.

Grocery Manufacturers of America, Inc., 1010 Wisconsin Avenue, N.W., Washington, D.C. 20007 • 202/337-9400 • Easylink 62913234

Green Mountain Orchards
P.O. Box 225
Putney, Vermont 05346
William H. Darrow, Jr.
Tel: 802-387-5851

Testimony of William H.Darrow, Jr., Green Mt. Orchards, Putney, Vermont, before the U.S. Senate Agriculture Committee July 30 1987, Washington DC.

My name is William H. Darrow, Jr., and I am the senior member of Green Mountain Orchards, the largest family owned and operated apple orchard in Vermont.

I am a second generation apple grower, who grew up on the farm, in the same house where one of my sons presently lives, while managing the farm and raising my grandchildren. I have served as President of the Vt. Horticultural Society, President of the New York and New England Apple Institute, President of the National Apple Growers' Association, and as Commissioner of Agriculture for the State of Vermont.

Today I want to express the apple growers' concerns about the rewriting of FIFRA, and to urge the drafters of that statute to consider the following points:

Vermont apple growers have a superb record of responsible chemical use. New England is the center of Integrated Pest Management, "IPM" for short. As part of our IPM programs, we trap insects in the orchard, to establish the minimum concentration of spray needed. We also examine the pest counts to see if we can get by with no spray at all. The majority of New England apples are grown on IPM programs. We respect the chemicals we use, and we use as little as we can. There is no incentive to use more than absolutely necessary. Sprays are expensive to purchase and expensive to apply. These high costs serve as a deterrent to the excessive use of sprays.

Amidst the heated and sometimes confusing controversies about chemical use, we apple growers are very concerned over the possibility that the new FIFRA may be drafted without considering the responsible use of chemicals by growers.

Fruit growers, as a group, also have a superb record of good health. I have been actively spraying every year since 1937. I have personally opened thousands of containers of pesticides over the past fifty years, and have spent thousands of hours operating spray rigs in our orchard. Such activities have had no negative effect that I or my doctor know of on the health of the four generations of my family that have lived in our orchard. Like many farm families, my family lives in a house located in the middle of an orchard. I grew up in that house, my children grew up in it, and now some of my grandchildren are growing up there. Our home is surrounded by the apple trees that we spray only as needed for pest control.

The simple fact is, fruit growers stand above the crowd in good health.

As you rewrite FIFRA, and are bombarded by lobbyists from various environmental and consumer advocacy groups, remember the splendid record of judicious chemical use by New England growers. Remember also their record of long and healthy lives over generations which have sustained the family farms of New England.

The big C, Cancer, has everyone scared. What is causing Cancer? Could pesticides be causing cancer? If you take a sample of apple growers involved with pesticide use for 10-20-30-40-50 years, there is absolutely no evidence that they are more cancer-prone than the general population. In fact, the opposite seems to be true.

Under FIFRA as it now exists, New England fruit growers have continued to be responsible in their use of chemicals, have continued to live long and healthy lives, despite their close proximity to such chemicals, and have battled increasing odds in sustaining their farms. Please take these facts into consideration as you draft a law that will have a heavy impact on our ability to keep producing quality produce.

In Summary:

1. Vermont Apple Growers are environmentalists; a genuine mix of serious environmentalists and yet pesticide users.

2. Two, three, and four generations of growers, continue to be careful stewards of our land. My apple-growing neighbor, Dwight Miller, is the seventh generation.

3. As farmers, we need certainty for marketing. The 1987 national apple crop is the largest on record. We are very concerned about our ability to market it successfully. 99% of our apples are sold out of state. Since our 1986 crop was shipped to 16 different states, we need national pesticide standards.

4. The apple growers of Vermont, of New England & NY, and the national apple growers, all request one national standard, only, for those chemicals which **today** pass every environmental test: **the** standard in the House of Representatives bill of Oct. 16, 1986.

5. On July 16, 1987, at the Mass. Fruit Growers Annual Summer Meeting, I was asked by Mass,, Conn., Maine, N.H., and Vermont growers, how can we convince Pat Leahy?

Please, Mr. Chairman, consider these facts, and help us obtain a National Standard.

Senator HARKIN. I guess our last witness, then, is John Hall, president of the American Wood Preservers Institute.

STATEMENT OF JOHN F. HALL, PRESIDENT, AMERICAN WOOD PRESERVERS INSTITUTE

Mr. HALL. Thank you. With me, Mr. Chairman, is Sherri Zedd, AWPI's director of congressional relations as well.

The wood preservers industry supports the reauthorization of FIFRA. We are the largest nonagricultural users of pesticides and have, over several years, experienced one of the Special Reviews of our chemicals. We support the process and the proposals for its improvement.

The wood preserving industry supported the bill which was approved by the House last fall, and supports the identical provisions which are included in this year's House legislation and in S. 1516. We recognize those as the compromise they were last year and support them in that vein. We recommend that they be the final action, not really the point of departure for further negotiations.

Our particular areas are listed in my prepared statements

INERT INGREDIENTS

While we favored a more simplified approach than that contained in S. 1516, we feel comfortable with the language in the current legislation that provides some discretion to the Administrator and with the report language that you approved last year in your consideration of similar legislation.

On the certification and training provisions, we also support that language and especially if it is accompanied by the language which was in the Senate report of last year.

While we originally opposed the opportunity for organizations which do not have an economic interest to request a hearing on the cancellation of a pesticide, we are satisfied with the requirement in the current legislation and the report language that these parties must present a substantial issue of fact.

With those as some of our important issues, we support the reauthorization of FIFRA, by this committee and a similar body in the House.

Referring to the ground water contamination provisions of S. 1419, we, like several of the other witnesses, prefer the language contained in the House bill, H.R. 2463, as being more realistic. It allows a distinction between the uses of the water and applies the control measures appropriate to the intended use of the water.

The GRGL provisions also in H.R. 2463, we think, are more reasonable and more capable of being adequately applied to the pesticide application. The most important issue for us is the reregistration amendments provision in H.R. 2463 which require the Administrator to consider the effects of voluntary actions or actions by others to reduce the impact of pesticide on ground water and also to assure the compliance with other environmental laws. That same consideration appears absent in the Senate version, and we recommend that the House considerations be included, so that we avoid having similar requirements placed on the users of pesticides in order to comply with the variety of environmental laws.

One particular concern to us is that we might well have a separate set of monitoring wells for the purpose of RCRA enforcement and another set for FIFRA.

That concludes the testimony. Again, we support reauthorization of FIFRA and recommend your consideration of the House version of the ground water contamination provisions. Thank you, sir.

[The prepared statement of Mr. Hall follows:]

Statement of John F. Hall, President
American Wood Preservers Institute
On S. 1516
THE FEDERAL INSECTICIDE, FUNGICIDE AND
RODENTICIDE REFORM ACT OF 1987
and
On S. 1419
TO PREVENT GROUNDWATER CONTAMINATION
BY PESTICIDES
Before the Committee on Agriculture,
Nutrition and Forestry
July 30, 1987

Mr. Chairman and Members of the Committee, thank you for the opportunity to present the views of the American Wood Preservers Institute (AWPI) on S. 1516, the Federal Insecticide, Fungicide and Rodenticide Act of 1987 and S. 1419, to prevent groundwater contamination by pesticides.

I am John Hall, president of AWPI. AWPI is a national organization representing the wood preserving industry on federal environmental regulations. Our members include manufacturers of wood preservatives and wood treaters.

The wood preserving industry is the largest non-agricultural user of pesticides and has a great deal of interest in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The industry has also experienced a Special Review (formerly called RPAR) which increased our familiarity with the statute.

A. AWPI Supports Various Provisions of S. 1516

In the climate of the 99th Congress's FIFRA reauthorization process, AWPI supported the version of H.R. 2482 which passed the House of Representatives on October 16, 1987. This version of the reauthorization represented the "least objectional" form of amendments to the statute that could have been negotiated in the climate of the waning days of the 99th Congress. AWPI was acutely aware that the provisions of this version of H.R. 2482 were the product of compromises achieved in a unique environment of negotiation between industry and public interest groups.

The House Committee on Agriculture recognized the value of the compromises that produced the October 16 version of H.R. 2482 as they incorporated most of the provisions of this bill into H.R. 2463 which would amend FIFRA. The bill you are considering today, S. 1516, contains many of the provisions of H.R. 2463 which affect the wood preserving industry. AWPI views these provisions of S. 1516 as a final point of compromise. The positions represented by the bill are the most drastic point away from our original views that we can support. Therefore, if these provisions of S. 1516 are viewed as the ultimate solution to the differences among the parties interested in FIFRA, not as a starting point for negotiation on possible amendments, we would again support the portions of S. 1516 which are identical to those of H.R. 2463.

This endorsement is based on several assumptions:

1. Inert ingredients. Although the industry favored a very simple provision providing the EPA administrator with

authority to regulate inert ingredients rather than the more elaborate scheme contained in S. 1516, AWPI was pleased that the minimum number of inert ingredients which must be placed on priority list is not "hard and fast". The introduction of discretion into this process whereby the Administrator does not have to place 50 inert on the list if he does not find a sufficient number meeting the requirements for listing, is a positive move.

AWPI requests that the following report language accompany this section as it clarifies the role of this section in regulating pesticide contaminants:

> The Committee intends that subsection (g) be construed in a manner that does not affect the authority of the Administrator to regulate ingredients that are not deliberately added to pesticides. More specifically, it is the Committee's intent that the Administrator remain free to regulate ingredients that are not deliberately added under whatever authorities are available. Thus the presence of any particular ingredient on the priority list established under subsection (g) should not be a basis for the Administrator not proceeding under other authorities. By the same token, however, the Committee intends that the Administrator exercise sound judgment in deciding whether to proceed under this subsection or under other existing authorities. In this fashion, the Committee expects the Administrator to weight the regulatory options available and choose those most consistent with the objectives of the bill while accommodating the reasonable concerns of registrations about unnecessarily duplicative approaches.

2. Certification and Training. The following report language which encourages reciprocity among the states should be included:

> In general, these amendments should be construed in a manner that encourages the states to employ reciprocity for the satisfaction of training requirements in situations where applicators are applying pesticides in more than one state. Reciprocity among the states should be considered an effective means of achieving a consistently high level of competency while encouraging the free flow of commerce across state lines.

3. Cancellation and Change in Classification on Labels:

Section 502, Cancellation and Change in Classification or Labels contains the following provision regarding the request for hearing on cancellation of a person without an economic interest in the pesticide:

> "(E) On receipt of a request for a hearing from a person without an economic interest in the

pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man and the environment.

AWPI accepts the concept of a cancellation hearing request by persons without an economic interest as long as the criteria set forth in this paragraph continues to be included in any version of FIFRA reauthorization considered by the Committee or the Senate.

* * *

AWPI Does Not Support S. 1419. Instead It Favors the Groundwater Protection Provisions Contained in H.R. 2463.

AWPI supports the goal of the reduction of contamination of pesticides by groundwater. However, the Institute does not support S. 1419, instead AWPI would favor amending S. 1516 with the groundwater protection provisions contained in H.R. 2463. AWPI is particularly concerned with the differences in the bills in the areas of: (1) definition of the resource to be protected, (2) definition of the Ground Water Residue Guidance Level (GRGL), (3) use of the GRGL, (4) monitoring requirements, (5) Federal State Role, (6) Scope of Registration Amendments.

1. Definition of the Resource to be Protected. H.R. 2463 distinguishes drinking water and potential drinking water from other ground water. It also includes hydrogeological and geographic considerations, depth to drinking water, and state criteria and guidelines. S. 1419 combines all groundwater defined as "underground sources of drinking water" to which it affords the same level of protection. The definition in S. 1419 could result in an enormous regulatory burden for pesticide registrants and for EPA. Therefore, AWPI favors the definition of the resource to be protected contained in H.R. 2463.

2. Definition of the GRGL. The GRGL in H.R. 2463 applies to the Maximum Contaminant Level (MCL) and other trigger numbers created under a new section of the Safe Drinking Water Act (SDWA). S. 1419 uses the MCL Goal (MCLG), a number which floats, which in many instances is zero and which is not set by rulemaking. The definition of the GRGL contained in H.R. 2463 is supported by AWPI.

3. Use of the GRGL. H.R. 2463 requires a different regulatory response depending on the groundwater use. If the GRGL is exceeded for current drinking water, a site specific response is called for. When the amount of pesticide in actual and potential drinking is approaching the GRGL (i.e. 30%), registration amendments are required. If the pesticide level in other groundwater exceeds the GRGL, EPA has the authority to initiate a special review.

S. 1419 uses its more stringent GRGL to initiate more onerous responses. If a pesticide exceeds this GRGL in an underground source of drinking water, EPA must institute a site specific ban of the product. Registration changes are required if a pesticide exceeds 25% of the GRGL in an underground source of drinking water in different locations. A special review may be initiated if the GRGL is exceeded in an underground source of drinking water. This review may also be triggered by pesticide detection below the GRGL in groundwaters which would be discharged to surface water causing an adverse effect on the environment.

AWPI believes that the use of the GRGL called for in H.R. 2463 provides an adequate protection of the groundwater resource. The Institute views the use of the GRGL advocated by S. 1419 as one which imposes excessive burdens on pesticide registrants and EPA.

(4) Monitoring Requirement. H.R. 2463 gives EPA the discretion to require registrants to monitor groundwater for pesticide contamination under certain conditions (e.g. to confirm detection in drinking water, to maintain a pesticide registration, etc.). S. 1419 has a nondiscretionary requirement for registrants to monitor groundwater if the pesticide may leach, if the EPA decides monitoring is necessary to maintain the registration, or if the pesticide is found in an underground source of drinking water over 50% of the GRGL. AWPI favors the more realistic monitoring requirements in H.R. 2463.

(5) Role of the States. H.R. 2463 calls for consultation and partnerships with the states. For example, when a site specific response is called for, state action is required to reduce the pesticide concentrations in drinking water wells over the GRGL. If the state fails to act, EPA must take "appropriate action."

S. 1419 uses federal primacy to establish programs to protect groundwater from pesticides in all 50 states. Governors are required to designate a state agency to develop and submit to EPA a program to prevent surface and groundwater pollution by pesticides. The program must be submitted in 2 years and contain certain information and schedules. If EPA disapproves the program, the state fails to submit one, or the state fails to enforce its program, the state may not register and must cancel any pesticide that may leach or have run-off.

AWPI favors the consultation/partnership role of EPA and the states advocated by H.R. 2463. It views the provisions of S. 1419 dealing with the role of the states as creating a massive and burdensome state bureaucracy.

6. Scope of Registration Amendments. H.R. 2463 requires EPA's Administrator to consider the effect of any voluntary actions by registrants or other persons, including actions by the State to prevent the GRGL from being exceeded, and compliance with other environmental laws. Therefore, efforts by a heavily regulated industry such as wood preserving to comply with other laws such as the Resource Conservation and Recovery Act (RCRA) or Superfund (CERCLA) might not be considered if a pesticide registration needed to be amended to protect the groundwater from contamination. This lack of consideration could result in a facility having separate monitoring wells to comply with FIFRA and RCRA. Inclusion of this provision in H.R. 2463 could also result in the EPA Administrator considering the differences in pesticide use in an industrial setting (such as in a wood preserving facility) and in agricultural activities. This provision is the most important portion of H.R. 2463 to AWPI and S.1419's lack of it is very distressing to the wood preserving industry.

Conclusion

Mr. Chairman, this concludes AWPI's prepared testimony. We welcome the opportunity to work together with Congress and with EPA in order reach the goal of protecting the environment. We will be happy to respond to any questions.

Senator **Harkin**. Thank you very much, Mr. Hall. I just have a couple of questions for the Farm Bureau, Fresh Fruit, and Food Processors. Your organization, first of all, the American Farm Bureau, your organization favors preemption of States' rights to set residue tolerances, and you presented a case for preemption in your testimony. Specifically what language do you support?

That contained in last year's House bill as the session ended or some other provision?

Mr. **Maslyn**. First of all, we support the establishment of States' rights in the tolerance setting process, and that is what the amendment in last year's House bill does. It sets up a mechanism whereby the States can participate in the establishment of tolerances. It does provide uniformity, though, once those tolerances are set with certain exceptions for certain circumstances.

Senator **Harkin**. So you support last year's House bill?

Mr. **Maslyn**. That is correct.

Senator **Harkin**. As it came out of session?

Mr. **Maslyn**. Yes, sir. The tolerance language.

Senator **Harkin**. How about the United Fresh Fruit and Vegetable Association?

Ms. **Fuquay**. Yes.

Senator **Harkin**. You support last year's?

Ms. **Fuquay**. Last year's tolerance language, correct.

Senator **Harkin**. The House bill as it came out?

Ms. **Fuquay**. On the tolerance language, yes.

Senator **Harkin**. That is what I am talking about. How about you, Mr. Hall?

Mr. **Hall**. That has not been an issue with us, but we did support the last year's House bill as was reported.

Senator **Harkin**. The Farm Bureau, under the House bill, EPA estimates a shortfall of $130 million for reregistration. You testified that reregistration is in the farmer's interest, but that fees should not be raised. How do you propose we make up the shortfall?

Mr. **Maslyn**. First of all, I did not say that fees should not be raised. We took the step last year of agreeing that fees should be levied for this particular purpose. We believe that the reregistration goal is a laudable one. It needs to be completed. It is in the farmer's interest. But we need to recognize that every penny that you levy on those registrants is going to come through to the user. It is going to come through to the family farmer in one way or another, and it is very difficult for those farmers to pass on those costs to the consumers.

So we have a natural reservation for the establishment of user fees. We believe particularly that pesticides in general are in the public interest. That is the reason we use them. And if there is shortfall, it ought to be a shared response, a shared expense from the farmer and the general public.

Senator **Harkin**. So that any shortfall just ought to come out of general revenues?

Mr. **Maslyn**. That is correct.

Senator **Harkin**. How would you feel?

Ms. Fuquay. Well, our position would be very close to the same thing because we do believe that pesticides are in the public interest.

Senator **Harkin.** I assume the other farmer who is here, Mr. Darrow, you would feel the same way?

Mr. **Darrow.** Yes, sir.

Senator **Harkin.** Thank you very much, all of you, for appearing today and taking time to give us your thoughts. If there is no other business before the committee, the committee stands adjourned at the call of the chair.

Editor's note: The statement of Pesticide Public Policy Foundation, dated January 6, 1988, is retained in the committee file.

[Whereupon, at 5:05 p.m., the committee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

COMMENT ON S. 1516
A bill to amend the Federal Insecticide,
Fungicide, and Rodenticide Act
TO THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
FROM THE
NATIONAL AGRICULTURAL AVIATION ASSOCIATION
Harold M. Collins
Executive Director
July 30, 1987

Mr. Chairman:

The National Agricultural Aviation Association (NAAA) extends its sincere appreciation to you and the members of the committee for providing this association with an opportunity to make comment on S. 1516, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

During a normal year this industry will apply seed, fertilizer, and crop protection chemicals to 180 million acres of this nation's land. Repetitive applications to some crops will increase the acres treated to more than 300 million. This work is accomplished with a high regard for safety. In fact, agricultural aviation has the lowest accident and fatality record of any segment of general aviation according to statistics compiled by the Federal Aviation Administration (see attached). We believe the industry's dedication to flight safety transfers equally to safe pesticide use. Especially via NAAA's Operation SAFE program and the ever improving state conducted certification and training programs. In this regard we believe it is worthy of note that the Federal Aviation Regulations (FAR's) which directly govern this industry have not been amended since 1965.

Also, NAAA wishes to commend the work of this committee which resulted in the 1978 FIFRA amendments. Since that time the pesticide user community has benefited from continuing education which, in NAAA's opinion, has improved the safety of pesticide user operations, benefited the public health, and reduced pesticide damage to the environment. While we all continue to strive for further improvements, we find it is most unfortunate that the public seems to be unaware of the agricultural community's achievements since the 1978 amendments. In our opinion the consequences of the committee's 1978 decisions have been productive and successful.

NAAA respectfully requests that the committee reconsider the testimony of the Environmental Protection Agency's Assistant Administrator for Pesticides and Toxic Substances, Dr. John E. Moore. If we interpret his comments correctly, as presented during the 1986 and 1987 hearings before the House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Operations (DORFA), the Agency already has the authority to accomplish much of the intent of Congress notwithstanding many of the currently proposed amendments to the FIFRA. It appears to NAAA that FIRFA amendments which would expedite EPA's product registration and reregistration process might reduce many public concerns which, at this time, lead to unnecessary requests for amendments that would complicate further the regulatory process and add substantially to the fiscal burden already imposed on the Agency as well as states.

Aerial applicators oppose the payment or creation of increased or new fees to EPA by any entity governed by the FIFRA. Fees imposed on any segment of the production agriculture community will be passed along in the chain of distribution between the crop in the field and the consumers' dinner plate. FIFRA is intended to protect the public health and environment. Therefore, we believe public funds should subsidize the Act, not funds from the regulated community.

NAAA supports continuation of indemnification payments under FIFRA. While we make no recommendations as to the source of such funds, we do believe that users need protection against financial losses caused by unpredictable government actions. The testimony by Mr. Dennis Burchett, Vice President, United Agri Products, on June 10, 1987 before the House DORFA Subcommittee clearly described the virtually impossible regulatory process which users are compelled to follow when overnight, a registered pesticide may be reclassified as hazardous solid waste. NAAA believes that in most cases, existing stocks of pesticide products in channels of trade, whose EPA registrations have been cancelled and/or suspended under the Act, could continue to be used for their intended purposes if appropriate label modifications were made that would minimize the health or environment effects that triggered the cancellation/suspension order. The continuing use of dinoseb in the Pacific northwest is a prime example of this concept.

This concept also has the following advantages:

1. Minimize the potential financial burden caused by indemnification.
2. Eliminate the need to gather and concentrate hazardous materials in one location.
3. Eliminate the exorbitant costs associated with the disposal of pesticides that become hazardous wastes because of regulatory action.

Few products available in our domestic marketplace have been so exhaustively studied for health and environmental effects as have been pesticides. This knowledge combined with modified use patterns that accomodate newly discovered concerns may well reduce the public fears of concentrated storage and the scientific unknowns associated with other disposal methods.

On page 109 of S. 1516. Sec. 702. the Administrator shall require some, but not all, users to prepare and maintain records regarding pesticide use. Similarly beginning on page 69, Sec. 401., some, but not all, users will be required to pass an examination which is intended to demonstrate knowledge of the safe use of pesticides.

It has been estimated that commercial applicators apply 30 percent of the 1 billion pounds of pesticides used annually. If this is true, then 70 percent of the pesticides may be used without documentation or demonstrated knowledge. This, in our opinion, does not serve the purposes of the Act. Especially when you consider that homeowners, according to government and private estimates, dispose of one third of the 121 million pounds of product they purchase annually (see attached). Dr. William Rathje, a professor at the University of Arizona has tabulated the type and quantity of trash that American families throw away each year. According to his study:

"Increasingly, the chemicals found in wells near landfills used for residential garbage resemble those found near toxic-waste dumps. That's because many of the substances in residential garbage -- pesticides, herbicides, paints and caustic cleaners -- are toxins. Eventually, they seep into the groundwater and are used for drinking and irrigation."

Beginning on page 122 of S. 1516, Sec. 1201 addresses criminal penalities levied on violators of the Act. We ask that the committee give additional consideration to the degree of financial punishment imposed by the Act based on the relative financial worth of each classification of potential violators. If the current basis for such fines was gross annual income and/or net worth of the violator, we seriously doubt that 2.5 aerial applicator businesses have the financial resources of a single registrant or that one aerial applicator business is 10 times financially stronger than its individual farmer/rancher customers. We believe that a more equitable system of fines should be developed.

Members of this industry have a strong and continuing concern for health and safety in the workplace. We have financed as well as participated in health studies of the people of this profession (see attached). As a group, we are voluntarily and repetitively exposed to pesticides at levels greater than the general public. If you support a dose-response relationship, we should be among the first to exhibit adverse health consequences. To date, these studies indicate that we fail to exhibit adverse health problems different from the general public. NAAA would strongly support a FIFRA amendment that would expand the study by USDA's Extension Service under National Agricultural Pesticide Impact Assessment Program (see attached).

Unfortunately there are individuals who exhibit abnormal sensitivities when exposed to some pesticides just as there are individuals who suffer from exposure to other natural and manmade components of our environment. On this basis we ask the committee to consider an amendment to FIFRA that would allow EPA to conduct a health study of commercial applicators and farmers/ranchers who are voluntarily and repetitively exposed to pesticides. Such a study would provide the public and regulators alike with meaningful data as opposed to the anecdotal information most often read and heard. Much of the FIFRA debate ultimately focuses on the protection of human health, so perhaps we would all benefit from a broad spectrum study of the user community that would analyze the effects of workplace and dietary pesticide exposure among this unique population.

NAAA supports amending the FIFRA to require the conduct of studies on container design and disposal. We believe this study should be broadened to include all forms of pesticide waste. In spite of existing federal statutes, pesticide users still lack efficient and affordable ways to deal effectively with pesticide wastes. In fact, the number of statutes that now exit which have regulatory control over pesticide use is confusing and burdensome to the user community. The number of state and federal government entities governing pesticide use seems to grow annually.

Next year, when the Endangered Species Act is implemented on the crop cluster group (see attached), some users will need to contact the U.S. Fish and Wildlife Service in order to determine whether or not specific pesticides may be used. NAAA would welcome an effort by this committee to amend the FIFRA in a manner that would give the House and Senate agricultural committees final control over existing and future legislation dealing with pesticides. We recognize the need for multiple jurisdictions but consolidation of these activities under one roof, the Senate and House agricultural committees, should provide for greater efficiency and productivity. Especially among the regulated community.

NAAA also would like to recommend the addition of a consultant category to the text of the amendments that begin on page 69 of S. 1516, Sec. 401. This association believes than any person who makes pesticide use recommendations for general and/or restricted use pesticides, but whose principle source of income is not derived from the actual application of such pesticides, should be required to provide the applicator and the grower with a written record of such recommendations and that a record of such recommendations be maintained for a period of not less than two years.

Finally, S. 1516 was not available to the public until July 27, 1987. With the Senate committee hearing on this proposed legislation scheduled for July 30, 1987, it is virtually impossible for NAAA to solicit, receive, and assemble association member comments from across the nation with this narrow timetable.

While NAAA's comments are based on historical information as well as similarities contained in H.R. 2463, the association does not believe that the public has been granted sufficient time to develop thoughtful and constructive comment on such important legislation. Indeed, we are unable to endorse S. 1516 until we can evaluate thoroughly this proposed amending legislation and to then compare it with other existing environmental statutes which also regulate pesticides.

Again, NAAA thanks the chairman and the committee members for your interest in our comments on S. 1516.

(Attached material follows:)

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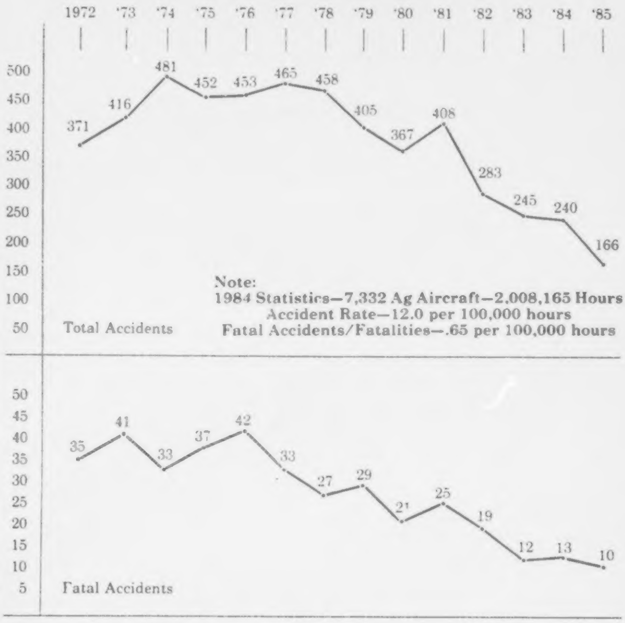
AERIAL APPLICATOR ACCIDENTS—TOTAL ACCIDENTS AND FATAL ACCIDENTS



Note:
1984 Statistics—7,332 Ag Aircraft—2,008,165 Hours
Accident Rate—12.0 per 100,000 hours
Fatal Accidents/Fatalities—.65 per 100,000 hours

Data from FAA preliminary reports

Chart prepared by B. A. Geier, aviation consultant for The National Agricultural Aviation Association

Agricultural Aviation asked 1985 "F.O.U.R. D.U.C." membership contest winners "What is the principal reason you became a member of NAAA?"

"I felt that I needed to support a part of the industry that helps support me; I believe in what NAAA does! I've been in ag aviation for four years and I hope to be in it for good. I felt that NAAA would help me stay in business longer. Ag aviation operators are just like farmers, we're very independent, but we are going to have to learn to work together more if we are to survive."

Steve Coker,
C&C Flying Service,
Valdosta, Georgia

Editorial

Pesticide Disposal—Where is the Logic?

It is entirely possible that the homeowner is the largest single source of environmental contamination by pesticides in this nation. Take a look at the pesticide use chart below and then consider the following thoughts.

Nearly 1 billion pounds of pesticides are used annually in the U.S. Based on the categories of land use, pesticides are applied to 100 percent of homeowner land, 24 percent of agricultural land, 18 percent of government and industrial land, and less than 1 percent of forest land. In total, 16 percent of this nation's land area is treated with pesticides annually.

If these statistics are accurate, then homeowners discard nearly 40 million pounds of pesticides (see chart*) annually. This solid waste is being accumulated in land fills and other disposal facilities in or around principal centers of our population. It seems to NAAA that the potential for human exposure and water contamination may be greatest in urban and city environments rather than rural areas.

The 1986 proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if passed, will require commercial pesticide applicators to receive special training in order to use *ANY* pesticide. Private applicators (homeowners) are *EXEMPT* from the need for training for all but restricted use pesticides. NAAA must question the logic of a regulatory process that exempts specific pesticide user groups from training and responsibility for their pesticide use and disposal.

Human health and environmental protection might be quickly and substantially improved if homeowners were required by law to either (1) undergo verifiable training to use any pesticide or (2) utilize the services of commercial applicators for pesticide applications. Option 2 has merit because commercial applicators would be unable (financially) to throw away 40 million pounds of pesticides annually. Therefore, an immediate reduction in solid waste generation and the subsequent accumulation of same in a limited number of disposal facilities in and around major population centers.

Lacking formal statistics, I would estimate that one third of all pesticide use is accomplished by commercial applicators. If this user group discarded 10 percent of each year's volume, which they can't afford to do, the trash pile would still be 7 million pounds lighter than the homeowner's.

Based on current thinking, it is the total volume of waste being generated that threatens our environment. Therefore, imposing federal and corresponding state statutes governing pesticides on a single user group defeats the purpose of the legislation. We must question why exemptions from the responsibility for proper waste disposal are provided to large numbers of pesticide users.

As a final thought, it has been suggested that a major source of pesticide presence in the Mississippi River is the result of farmland drainage. However, consider how many metropolitan centers are located on or near the banks of America's largest river. Maybe it is time to give a little credit for pollution to the other folks. Then again, that could be political suicide.

Harold Collins

LAND USE CATEGORY	TOTAL ACRES AVAILABLE (millions)	TOTAL ACRES TREATED ANNUALLY (millions)	TOTAL LBS. APPLIED ANNUALLY (millions)	AVERAGE NO. OF LBS. APPLIED/ACRE ANNUALLY
Agricultural lands	1,168.8	281.7	750.2	2.66
Government & Industrial lands	370.7	69.2	121.0	1.75
Forest lands	716.6	4.9	8.8	1.78
Household lands	9.9	9.9	121.0	12.24*
TOTAL	2,266.0	365.7	1,001.0	

The above information was derived from published USDA and private industry statistics

*Apparently, as much as a third of the pesticides homeowners purchase is never applied and consequently, ends up in the trash. If this disposal estimate is correct, actual homeowner use of pesticides would be reduced to 8.13 pounds per acre annually.

Editorial

Endangered Species Restrictions

Have you ever heard of the Blunt-nosed leopard lizard? I can assure you that growers and commercial applicators who apply crop protection chemicals in Merced County, California will hear a lot about this particular critter in the near future.

The reason for publicity and concern is the fact that the Blunt-nosed leopard lizard is but one of 306 endangered species around the nation that must be protected at any cost. As you may suspect, the initial cost of protection will be levied on American agriculture, in many areas, by preventing the use of numerous chemicals vital to crop production.

The current habitat (range) of this lizard, according to the U.S. Fish and Wildlife Service (FWS), includes much of the land in 10 California counties. According to the California Department of Food and Agriculture the 1986 dollar value of barley, corn, cotton, silege and wheat crops in Merced County alone exceeded $68 million. We can only guess at the value of these same crops next year if destructive insects, plant diseases, or competing weeds can no longer be controlled with crop protection chemicals.

The chart below identifies specific sites of treatment (clusters) that will be impacted by the Endangered Species Act (ESA). Anyone interested in learning whether or not a specific county will be involved with the ESA should contact FWS, the Environmental Protection Agency (EPA) or the County Extension Office.

The implementation of the Act falls to FWS but EPA will enforce it. The list below names just a few of the 68 chemicals involved that jeopardize one or more of 45 species of plants and animals in the crop cluster.

2,4-D
Atrazine
Captan
Carbaryl
DEF
Diazinon
Dimethoate
Malathion
Methyl Parathion
Parathion
Permethrin
Trifluralin

Current draft language being considered for addition to product labels is as follows:

Endangered Species Restrictions

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of federal laws. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

Before using this pesticide in the following counties you must first obtain the (appropriate cluster) Endangered Species Bulletin. The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your local pesticide distributor, your county agricultural headquarters or the appropriate regional office of either the U.S. Fish and Wildlife Service or the U.S. Environmental Protection Agency. *THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.*

Implementation of the chemical labeling requirements for the crop cluster is currently scheduled for the spring of 1988. Between now and then some important questions need to be addressed.

1. Has production agriculture actually been identified as a significant cause of population reductions among endangered species?
2. Does implementation of the ESA deprive the economic freedom of land owners to use property and subsequently impair fair competition in the marketplace?

Harold Collins

CLUSTER DATA

	Number of Pesticides		Species Jeopardized		Number of Affected	
Cluster	Total	Restricted [1]	Number	Percent [2]	States	Counties
Forest	24	4	53	17.4	24	308
Mosquito Larvicide	9	3	83	27.2	21	136
Rangeland	33	7	133	43.6	24	199
Crop	68	11	36	11.8	18	135

1] Of total number, these are classified as Restricted Use
2] Percent of the total number of species jeopardized for all clusters

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Spontaneous Abortions, Stillbirths, and Birth Defects in Families of Agricultural Pilots

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ABSTRACT. Families engaged in Agricultural Aviation (314) and cooperating sibling families, not occupationally exposed to pesticides (178) provided information, in response to a questionnaire, on their general health status and pregnancy outcomes. These two groups were comparable in age, height, weight, and years of education. Statistical evaluation confirmed the null hypothesis with respect to total pregnancies, number of male or female chldren, spontaneous abortions, and birth defects.

THE UBIQUITOUS NATURE of many pesticides, demonstrable via exceptionally sensitive analytic technology, assures some level of pesticide exposure for the general public. In the case of 2,2-di[*p*-chlorophenyl]-1,1,1-trichloroethane (DDT) and other persistent pesticides this status has been verified by numerous studies.[1-6]

Possible adverse health effects of both public and occupational exposures to DDT were explored in 1944.[7,8] An investigation of the storage and excretion of DDT and its metabolites in man was completed a decade later.[9] Studies of qualitative and quantitative occupational exposures to pesticides have been abundant since the 1960s.[10-13]

Because of the exceptional acute toxicity of some organic phosphorus and carbamate pesticides, they have been the subject of extensive research.[14-18] These studies substantiate that occupational exposures to pesticide applicators are significantly higher than the exposures experienced by the public.

Although there have been numerous investigations[19-26] of possible acute and chronic effects associated with occupational exposures to pesticides, few studies have involved reproductive effects.

Possible adverse reproductive effects must be considered in toxicology, and such effects are apparently among those most feared by the public. Unfortunately, reproductive studies in animals do not exclude the possibility that human beings may be more susceptible than test animals to certain compounds. One startling example of such susceptibility is the case of dibromochloropropane.[27] Another pesticidial fumigant chemical, ethylene dibromide, has also been the subject of investigation for its reproductive toxicity.[28] The design and conduct of studies involving the hazards to reproduction of occupational chemical exposures are exceptionally complex.[29-31] The most easily obtained information that may have some significance to this subject is sex ratio, fertility, spontaneous abortions, and birth defects.[30] In addition to the impact of occupational chemical exposures on reproduction are the complications of alcohol, tobacco, over the counter and prescription drug use, anaesthesia, and radiation exposures. Increasing interest is being shown in the subject of reproductive hazards in the work place.

The present study was initiated in 1978 at the request of the National Agricultural Aviation Association after their request for such a study was rejected by the United States Department of Agriculture, the Environmental Protection Agency, and the Federal Aviation Association. Agricultural Pilots, the most stable employment group in this industry, were selected because previously cited investigations indicated that their exposures are sufficient to make such a study meaningful.

METHODS

The National Agricultural Aviation Association provided membership lists for 1978 as a source for the selection of a study group. Based on this membership list a target group of 75% of the estimated number of pilots was established. Questionnaires (780 sets) were provided to each state and regional association affiliated with the national association for distribution at local meetings or by other methods available. A "questionnaire set" included a questionnaire to be completed by an Agricultural Pilot and his spouse, and an identical questionnaire to be sent by the pilot volunteer to a sibling (and spouse) who had never been engaged in agricultural aviation. The sibling control group was chosen to assure a close demographic match and to control for genetic factors. Matched pair evaluations were employed only when the data warranted this approach. The numbers of spouses do not match because of divorce, death, etc. The responses to this approach appear in Table 1. Participation was voluntary, which resulted in "self-selection." Direct mailing to individuals selected randomly would have resulted in lower returns since the responses would still have been voluntary.

Table 1.—Number of Responses Received from the Various State and Regional Organizations of the National Agricultural Aviation Association

	Geographical Areas					
Group	1	2	3	4	Total	%*
Pilots	47	46	84	137	314	40
Control Males†	29	20	31	70	150	19
Pilots' Wives	32	34	70	108	244	31
Control Wives†	54	20	33	71	178	22

NOTES: Area 1: Maine, New Hampshire, Vermont, Connecticut, New York, Pennsylvania, Massachusetts, Maryland, New Jersey, Delaware, Virginia, West Virginia, Rhode Island, Ohio, Illinois, Indiana, Michigan, Wisconsin, Kentucky; Area 2: Tennessee, North Carolina, South Carolina, Georgia, Alabama, Florida, Mississippi; Area 3: California, Arizona, New Mexico, Texas, Arkansas, Louisiana, Oklahoma; Area 4: Minnesota, Iowa, Kansas, Nebraska, Missouri, North Dakota, South Dakota, Colorado, Montana, Idaho, Utah, Nevada, Oregan, Washington, Wyoming.

* Percent of target group responding.

† Control males are brothers and brothers-in-law. Control wives are sisters and sisters-in-law.

Table 2.—Years of Experience in Agricultural Aviation

Years	No. Pilots	%
1–5	33	11
6–10	74	24
11–15	55	18
16–20	22	7
> 21	128	41

Spontaneous abortion and stillbirth information provided by the responses of females have been used since the sibling females had the higher response rate as compared with the males. Sex ratio data were provided by male respondents. Birth defect data were requested from male respondents only.

RESULTS

The data in Table 2 indicate the general agricultural experience of this group of pilots. The fact that the majority have more than 15 yr of agricultural aviation experience is not unexpected since such a highly skilled group might be expected to be stable in employment. Information concerning the number and frequency of pesticide intoxications resulting in lost work days in the pilot group have been summarized recently.[32]

Weight, height, age, and educational level are summarized in Table 3. Inspection of these data does not indicate any statistically significant differences with regard to the characteristics recorded.

The data for overall reproductive performance, based on data supplied by female respondents of these two study groups, appear in Table 4. Chi square analysis of the data does not reveal any statistically significant differences between these two study groups with regard to age distribution or the number of live births. Comparisons of the spontaneous abortions and stillbirths reported by these two study groups likewise fail to reveal any statistically significant differences.

The data on sex ratios, obtained from the male respondents, appear in Table 5 on the basis of the decade of the births reported. These data do not suggest any differences in the number of children or the sex ratios based on the group data for the period covered. Com-

Table 3.—Average Characteristics of the Study Groups

	Pilots	Control Males	Pilots' Wives	Control Females
No. in Group	314	150	244	178
Characteristic				
Age (yr)	44	43	42	42
Education (yr)	13	14	13	14
Height (in)	70	70	65	65
Weight (lb)	184	182	134	138

parison of these data with those reported by the spouses in Table 4, support the similarity of the two groups.

Since the predominate occupational pesticide exposures were experienced by the pilot group, information regarding birth defects was obtained from male respondents only. These data were obtained in the questionnaire in response to the following: "If any of your children were born with or later developed any of the following conditions, please write in the number of the child (from question 8) and his/her age when the condition developed." The respondent was provided with a tabular list of 33 possible defects and the usual "other" category. Using this information from unmatched samples, i.e., not every pilot had data from a brother's or sister's family, the data in Table 6 were obtained.

Grouping the reported defects, based on the data from the unequal population sizes in Table 6 into major, musculoskeletal, and other significant defects for statistical analysis did not reveal any significant differences using the chi square analysis.

The number of individuals in a group reporting any defects has a greater significance than the total number of defects reported from the group. The use of the epidemiological concept of case matching provides a more precise approach to phenomena of low frequency such as birth defects. The data in Table 7, therefore, provides an additional basis for not rejecting the null hypothesis in the case of the birth defects.

DISCUSSION

Despite the fact that responses were less than targeted, the data reported here shed some light on the reproductive hazards possibly associated with pesticide

Table 4.—Reproductive Performance* in the Two Study Groups

	Control Wives		Pilots' Wives	
Number of Respondents	178		244	
Number of Respondents Reporting any Pregnancies	133		221	
Age Range	Pregnancies	Spontaneous† Abortions	Pregnancies	Spontaneous Abortions
15–19	30	3	61	3
20–24	166	17	271	17
25–29	115	10	184	10
30–34	66	10	99	17
35–39	15	3	31	1
40–44	4	NR	5	NR
$\chi^2 = 17.8896$, $df = 15$, $P = .27$				
SUMMARY				
Live births	350		588	
Spontaneous abortions and stillbirths	43		60	
$\chi^2 = 0.7509$, $df = 1$, $P = .6094$				
Live births per respondent reporting any pregnancies	2.63		2.66	
Live births per pregnancy	0.89		0.91	

* Pregnancies include those before marriage to the respondent spouse.
† Includes stillbirths.

Table 5.—Decade of Children's Birth and Sex of Child*

	Pilot		Control	
Decade	Male	Female	Male	Female
1921–30	4	1	1	3
1931–40	1	4	2	2
1941–50	37	44	23	16
1951–60	124	98	36	37
1961–70	110	124	59	59
1971–80	95	88	41	33
$\chi^2 = 19.0528$, $df = 15$, $P = .2135$				
Ratio of male/female	1.03		1.08	

* Data reported by male respondents.

exposures. To the extent that weight, height, age, and educational level are valuable socioeconomic indicators, the concept of sibling control groups appears justified. Data cited on the acute intoxications causing lost work days[32] indicate that exposure potentials are considerable. Although the overall reproductive performance of the pilots and spouses are not in essence different than that reported by their siblings, the statement, ". . . in general it is unusual for reproductive toxic effects to be observed at otherwise non-toxic doses."[30] caused us to review the responses from those individuals reporting pesticide intoxications. We failed to find any relationship between pesticide intoxication, as reported, and reproductive performance.

The fact that spontaneous abortion rates—10.9% for control wives and 9.26% for pilot wives—were considerably lower than the commonly accepted 15%[29] may well be a reflection of the socioeconomic status of these groups. There was certainly no adverse effect on spontaneous abortion rates experienced by the pilot groups.

The size of the study groups makes it impossible to make meaningful comparisons with general population birth defect data. The internal comparisons between the two male study groups failed to reveal any significant differences. It would generally be remarkable to see differences in birth defects without rather parallel differences in the spontaneous abortion rates.

Although data on the use of tobacco, alcohol, a variety of prescription drugs, etc. were collected it is pointless to examine these data in detail in view of the lack of differences in sex ratios, spontaneous abortions, and birth defects. Data on general family health, particularly children's health, were also obtained. Our evaluation of these data have not revealed any remarkable differences. We were surprised to discover five female pilots employed in agricultural aviation. This group is too small at present to be evaluated separately.

Table 6.—Birth Defects Reported by Pilots and Control Males

Ever Married	Pilots 306	Control Males 138
Defects		
Hydrocephalus	1	0
Down's syndrome	1	0
Cerebral palsy	2	2
Deafness	1	1
Hare lip/cleft palate	1	0
Congenital heart defect	7	0
Pyloric stenosis	1	2
Occluded/duplicated intestine	3	1
Cystic fibrosis	1	0
Displaced kidney	2	1
Malformed reproductive organs	5	2
Defective hip	3	0
Bone cysts	1	1
Club foot	2	1
Severe bow legs	0	1
Congenital hernia	5	7
Other	7	2
Total defects	43	20
Parents reporting defects	47	17
$\chi^2 = 0.4505$, $df = 1$, $P = .5095$		
Defects per 100 live births	5.9	6.4

Table 7.—Evaluation of Pair-Matched Individuals Reporting Birth Defects

		Pilots	
		yes	no
Control males	yes	2	17
	no	19	77

$\chi^2 = 1.282$, $df = 1$, $P = .2567$; relative risk = 19/17 = 1.12.

CONCLUSIONS

Although it is not possible to document the specific pesticide exposures of the group of agricultural pilots providing data for this study, the fact that their overall exposures to pesticides are higher than those sustained by the general population is well established. Occupational data available from the sibling group did not indicate any occupational pesticide exposure.

There were no significant differences between the pilot families and their siblings' families regarding age, weight, height, education, children per couple, sex ratio, spontaneous abortions, ages of live births or other termination of pregnancy, or number of birth defects among their offspring. The group sizes were small and there is no certain basis for concluding that there is a complete absence of a pesticide effect in the reproductive data collected and evaluated.

Because of the increasing probability of female exposures in the work place we strongly recommend that, to the extent it is consistent with biological facts, identical data be obtained from both male and female respondents.

* * * * * * * * * *

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REFERENCES

1. Morgan, D. P., and Roan, C. C. 1970. Chlorinated hydrocarbon pesticide residues in human tissue. *Arch Environ Health* 20: 452–57.
2. Casarett, I. J.; Fryer, G. C.; Yeager, W. L., Jr.; and Klemmer, H. W. 1968. Organochlorine pesticide residues in human tissue. *Arch Environ Health* 17: 306–11.
3. Dale, W. E., and Quinby, G. E. 1963. Chlorinated insecticides in the body fat of people in the United States. *Science* 142: 593–95.
4. Laug, E. P.; Kunze, F. M.; and Prickett, C. S. 1952. Occurrence of DDT in human fat and milk. *Arch Ind Hyg Occup Med* 3: 245–46.
5. Curley, A.; Burse, R. W.; Jennings, E. C.; Villanueva, L.; and Akazaki, K. 1973 Chlorinated hydrocarbon pesticides and related compounds in adipose tissue from people of Japan. *Nature* 242: 338–40.
6. Bevenue, A. J.; Wilson, J.; Cassarett, L. J.; and Klemmer, H. W. 1967. A survey of pentachlorophenol content in human urine. *Bull Environ Contamin Toxicol* 2: 319–32.
7. Neal, P. A.; von Oettingen, W. F.; Smith, W. W.; Malmo, R. B.; Dunn, R. C.; Moran, H. E.; Sweeny, T. R.; Armstrong, D. W.; and White, W. C. 1944. Toxicity and potential dangers of aerosals, mists, and dusting powders containing DDT. *Public Health Rep* 177: 1–32.
8. Neal, P. A.; Sweeny, T. R.; Spicer, S. S.; and von Oettingen, W. F. 1946. The excretion of DDT in man, together with clinical observations. *Public Health Rep* 61: 403–09.
9. Hayes, W. J., Jr.; Durham, W. F.; and Cueto, C. 1956. The effect of known repeated oral doses of chlorophenothane (DDT) in man. *JAMA* 162: 890–97.
10. Durham, W. F., and Wolfe, H. R. 1972. Measurement of the exposure of workers to pesticides. *Bull WHO* 26: 75.
11. Arterberry, J. D.; Durham, W. F.; Elliott, J. W.; and Wolfe, H. R. 1961. Exposure to parathion. *Arch Environ Health* 3: 476.
12. Ganelin, R. S.; Cueto, C.; and Mail, G. A. 1964. Exposure to parathion. *JAMA* 188: 807.
13. Roan, C. C.; Morgan, D. P.; Cook, N.; and Paschal, E. H. 1969. Blood cholinesterase, serum parathion concentrations and urine *P*-nitrophenol concentrations in exposed individuals. *Bull Environ Contamin Toxicol* 4: 362–69.
14. Hayes, A. L.; Wise, R. A.; and Weir, F. W. 1980. Assessment of occupational exposure to organic phosphates in pest control operators. *Am Ind Hyg Assoc J* 41: 568–75.
15. Copplestone, J. F.; Fakhari, Z. F.; Miles, J. W.; Mitchell, C. A.; Osman, Y.; and Wolfe, H. R. 1976. Exposure to pesticides in agriculture: A survey of spraymen using dimethoate in the Sudan. *Bull WHO* 54: 217–23.
16. Durham, W. F.; Wolfe, H. R.; and Elliott, J. W. 1972. Absorption and excretion of parathion by spraymen. *Arch Environ Health* 24: 381–87.
17. Hartwell, W. V., and Hayes, G. R., Jr. 1965. Respiratory exposure to organic phosphorus insecticides. *Arch Environ Health* 11: 564–68.
18. Nash, R. G.; Kearney, P. C.; Maitlen, J. C.; Sell, C. R.; and Fertig, S. N. 1982. Agricultural applicator exposure to 2,4-dichlorophennoxyacetis acid. ACS Symposium No 182, *Pesticide Residues and Exposures.*
19. Ortlee, M. F. 1958. Study of men with prolonged occupational exposure to DDT. *AMA Arch Ind Health* 18: 433–40.
20. Stein, W. J., and Hayes, W. J., Jr. 1964. Health Survey of pest control operators. *Ind Med Surg* 33: 549–55.
21. Laws, E. R.; Curley, A.; and Biros, F. J. 1967. Men with extensive occupational exposure to DDT. *Arch Environ Health* 15: 766–75.
22. Ott, M. G.; Holder, B. B.; and Olson, R. D. 1980. A mortality analysis of employees engaged in the manufacture of 2,4,5-trichlorophenonxyacetic acid. *J Occup Med* 22: 47–50.
23. Menz, M.; Leutkemeier, H.; and Sachsse, K. 1974. Long term exposure of factory workers to dichlorovos (DDVP) insecticide. *Arch Environ Health* 28: 72–76.
24. Wang, H. W., and MacMahon, B. 1979. Mortality of pesticide applicators. *J Occup Med* 21 741–44.
25. Wang, H. W., and MacMachon, B. 1979. Mortality of workers employed in the manufacture of chlordane and heptachlor. *J Occup Med* 21: 745–48.
26. Poland, A. P.; Smith, D.; Metter, G.; and Possick, P. 1971. A health survey of workers in a 2,4-D and 2,4,5-T plant. *Arch Environ Health* 22: 316–27.
27. Whorton, M. D., and Milby, T. H. 1980. Recovery of testicular function among DBCP workers. *J Occup Med* 22: 177–79.
28. Wong, O.; Utidjian, H. M. D.; and Karten, V. S. 1979. Retrospective evaluation of reproductive performance of workers exposed to ethylene dibromide (EDB). *J Occup Med* 21: 98–102.
29. Buffler, P. A., and Aase, J. M. 1982. Genetic risks and environmental surveillance: Epidemiological aspects of monitoring industrial populations for environmental mutagens. *J Occup Med* 24: 305–14.
30. Barlow, S. M., and Sullivan, F. M. 1981. Reproductive hazards and industrial chemicals. *Ann Occup Hyg* 24: 359–61.
31. Sever, L. E. 1981. Reproductive hazards of the workplace. *J Occup Med* 23: 685–89.
32. Roan, C. C.; Olds, K. L.; and McIlnay, C. Q. 1982. Crop, pesticide use and pesticide related occupational illness of agricultural pilots. *World Ag Avia* 9(3): 24–25.

ASSESSING PESTICIDE IMPACT ON HUMAN HEALTH IN NEBRASKA

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Health screenings and surveys of a Nebraska Aviation Trades Association volunteer cooperator group were conducted as one component of a project aimed at Assessing Pesticide Impact on Human Health in Nebraska. This comprehensive evaluative study was conducted as part of the National Agricultural Pesticide Impact Assessment Program, a program of the Extension Service, U.S. Department of Agriculture.

Over a three-year period commencing in February 1983, we prospectively examined 125 commercial pesticide workers (57 aerial applicators and 68 structural applicators) and 33 controls. The pesticide workers consisted of two groups: 1) aerial applicators whose exposure to pesticides was primarily during summer months, and 2) structural applicators whose exposure was continuous.

The aerial applicators were examined twice a year; the structural applicators were examined once a year. The controls, who were selected from a group of individuals living in the same geographic areas as the aerial applicators but not occupationally exposed to pesticides, were examined once a year. The examinations consisted of a thorough health history, a complete physical exam, a complete blood count, a blood chemistry profile, audiometry, vision testing, spirometry, and serum cholinesterase levels.

A total of 407 examinations were performed. All participants were male, the average age of the pesticide workers was 38 (40 for the aerial applicators and 36 for the structural applicators), the average age of the controls was 39.

The aerial applicators tended to have a more frequent history of accidents or injury, more ENT complaints, and worse hearing; however, they had fewer cardiac and pulmonary complaints and less reported illness when compared to controls. None of these findings were statistically significant. No differences were seen in the blood chemistry values, complete blood counts, or cholinesterase levels between any of the groups.

The aerial applicators tended to have higher body weight, alcohol intake and SGOT levels at the winter (unexposed) exam, but the SGOT values were within the normal range and none of the differences were statistically significant.

We concluded that in our study groups, the incidence of health problems in pesticide workers is the same as controls. In workers with periodic exposure to pesticides, no differences could be documented in their general health between exposed and unexposed periods. When health problems were identified, they were overwhelmingly due to the same problems which adversely affect the health of the general population; i.e.: minor musculoskeletal and upper respiratory problems, accidents or tobacco and alcohol related diseases. The study is limited by its small size and differences in the groups could have been missed, especially in the areas noted above. It appears unlikely, however, that these trends would be explained by pesticide exposure.

Both the initial physical examinations and survey of the NATA cooperators were conducted during the association's annual state convention. Among the 57 volunteer participants there were five non-Nebraskans. The median age group was

30-39 years; more than half of the group had 11 or more years in agricultural aviation and one in five had more than 20 years in the business. All were certified pesticide applicators and nearly two-thirds of the group said 50 percent or more of the pesticides they applied were restricted use products. Fifteen members of the group (26%) said they had been made ill at some time from working with pesticides and well over half reported that they knew someone else who had been made ill from working with pesticides. Only eight persons (14%) said they always used label-specified safety clothing and equipment when handling pesticides; however, 25 (44%) said they did so "frequently."

The second and third health screenings and surveys were conducted respectively midway through the 1983 application season and during the February 1984 association convention.

Of the 47 participants in the second screening/survey, three persons said they had been ill at some time since the first screening. One of the three said the illness was definitely pesticide-related and a second said his was "possibly" attributable to pesticides; the third was not pesticide-related. Nine persons (19%) reported they "always" used label-specified safety equipment, while 11 (23%) said they used it "frequently."

A total of 50 responses were tabulated after the third (February 1984) screening/survey. Two persons reported having been ill since the preceding screening/survey and only one said the illness was "possibly" attributable to pesticide exposure. There was no significant difference in the numbers and percentages of persons who said they followed product label directions for the use of safety equipment; nine (18%) "always" used it; 19 (38%) used it "frequently."

Four of the 41 participants who returned completed surveys after the fourth screening/survey (August 1984) said they had been ill at some time during the preceding six months. None of the illnesses were reported to be pesticide related. Again, the numbers and percentages of persons using label-specified safety equipment were not significantly different from the preceding survey; seven (17%) said they "always" used it, and 10 (24%) said they "frequently" used it.

The fourth survey also included items on changes in attitudes concerning pesticide usage and practices related to handling and application. Respondents were asked to characterize their present level of concern for 1) their own health, 2) persons residing in the vicinity of application sites, and 3) the environment in general. The majority in each case said there was "no change."

Participants also were asked to compare present practices with those used prior to the start of the project with respect to: 1) reading pesticide product label before use, 2) using label-specified protective clothing/equipment, 3) calibrating the application system of the aircraft, 4) wearing hearing protection, and 5) considering meteorological conditions before applying pesticides. The overwhelming majority in each case said there was no change; the balance said they employed the practice "more frequently." Four persons reported they were exercising more care in securing stored pesticides and two said they were using more precautions in empty container disposal.

Changes in health-related practices included dieting (3), quitting or trying to quit smoking (11), and starting to wear hearing protection while flying (7).

The number of participants in this study is an obvious limitation. However, we can conclude that aerial pesticide applicators are occupationally exposed to pesticides with potentially serious negative consequences. Extreme caution is warranted when using highly toxic products. In addition, despite the fact that many operators use "closed" systems to load their aircraft, label-specified protective clothing/equipment should be worn to reduce the potential for exposure to pesticides.

July 27, 1987

Honorable Patrick Leahy
Chairman
Committee on Agriculture,
  Nutrition and Forestry
U.S. Senate
Room 328 A
Russell Senate Office Building
Washington, D.C. 20510-6000

Dear Senator Leahy:

As a concerned citizen, an Iowan and an environmentalist, I would like to make known my concerns on several facets of the FIFRA amendments currently before the United States Congress.

As a lifetime resident of the State of Iowa, and an attorney who often has contact with various segments of the agricultural community, I am well aware of the role agricultural chemicals directly and indirectly play in both the livelihood of many of the individual agricultural producers of this state and the state's general economy.

I understand the reliance of the grower upon chemicals to control insects and weeds which allow him to produce economical crop yields. It is my opinion that new technologies in research and development are essential to produce more environmentally compatible chemicals. As an environmentalist and Sierra Club member, I am deeply concerned with the protection of the natural resources of our land, air and water. It is my belief that a balanced partnership must be forged between modern chemical technology and environmental protection.

Toward that end, I am greatly concerned about the potential in Congress for changing the way FIFRA treats data compensation. What the generic pesticide industry is lobbying for is a free ride on the research companies. Although this approach may be touted as a means to save the individual producer money, it appears to be cost ineffective in the long range: costing producers, consumers and the environment. This cost of relaxing the standards on data compensation will manifest itself in several major ways:

1. The failure to require data compensation from the generic producers may severely reduce the dollars available to fund grants for university research, testing and studies. This in turn will reduce the development of more environmentally compatible pesticides, the ongoing testing of existing products and the assurance of environmental safety.

2. On a short term basis, the lower cost of the generics may increase their usage, but may also actually reduce many of the benefits traditionally available from the chemical manufacturer--service after the sale, further product research, general technical assistance, greater training and certification. Accordingly, the perceived short-term economical benefit will be offset by much greater, long-term costs.

3. Finally, one cannot ignore the potential harm to the environment from the increased use of generic products. The fact the chemicals which are going "off patent" represent "aged" chemicals in the industry and past technology (which has since been improved) is of concern in that these chemicals are the most commonly found pollutants in groundwater. Accordingly, the use of these generics may open the floodgates to additional problems - problems which without data compensation will not be rectified through additional research. Without data compensation, manufacturers would have little encouragement to engage in new research, especially that research which would assist in the protection and preservation of the environment.

It is my hope that in considering the amendments to FIFRA, you will give weight to these comments and concerns, and include my statement in the printed hearing record. The future of many growers, the nature of agriculture in the years to come, and environmental integrity as a whole may be affected by FIFRA's treatment of data compensation.

Patricia A. Kelley
321 E. Walnut
Suite 200
Des Moines, Iowa 50309

July 27, 1987

Honorable Patrick Leahy
Chairman
Committee on Agriculture,
Nutrition and Forestry
U.S. Senate
Washington, D.C. 20510

Dear Senator Leahy:

I am a farmer from Red Oak, Iowa. I've been in farming for 14 years, growing soybeans and corn, and as such have an extraordinary dependency on agricultural chemicals.

When you announced the July 30 hearings on pesticide legislation, I called your Committee to ask if I could be allowed to testify. I was told that the Farm Bureau was already scheduled as a witness. When I explained that I intended to testify on a part of the FIFRA bill which Farm Bureau didn't plan to discuss, I was told the list of witnesses was too full to accommodate me.

This is disappointing because I know there will be at least one witness who will suggest that changing the data compensation section of FIFRA will stimulate cost savings to farmers. This is an argument which is immediately appealing to Members of Congress, but it deserves closer scrutiny.

Will you please give consideration to my commments on this important section of FIFRA (attached) and include my statement in the printed hearing record?

Sincerely,

Roger Carlson
Rural Route 1
Red Oak, Iowa

TESTIMONY BY ROGER CARLSON,
FARMER
RED OAK, IOWA

Before the Senate Agriculture Committee
July 30, 1987

Mr. Chairman, I am Roger Carlson, a family farmer of 14 years. I farm corn and soybeans. I'm by necessity a user of agricultural chemicals - some of them generic and some produced only by research intensive companies.

I am not here to pick between the two kinds of products, but I want you to know how farmers like myself feel about them and more to the point, what the data compensation provision of the FIFRA law means to farmers.

There will be testimony that elimination of data compensation will lower prices. Without understanding all of the implications of this elimination, a farmer may initially favor this. However, I believe once they understand all sides of this issue, they will be strongly in favor of data compensation.

The non-research industry, with or without data compensation, will stay in business and will price their products approximately 10% lower than the products of

research companies. On a per product basis, this savings may be equivalent to only a 1% or 2% savings per acre which is insignificant compared to the value we now receive, and in the future will receive from additional research.

My second point is that I have used both generic and non-generic agricultural chemicals. It is important to know why I would purchase products from the basic research companies. The answer is simple and overlooked in debate on this issue - to do so is to buy the technical expertise of that company and product support. By that I mean that if I have a problem I don't feel the non-research company will have the technical background and people to help me, but the research company will. They will because they spent the years to develop and understand that product. When I have problems of any kind with a product on how to apply it, etc., I can count on the help of the research firm's technical service representatives - I cannot expect the same assistance from non-research companies. The research company can advise on when to apply products, what types of products are compatible, the effect of certain products on soil, reentry times, and more. They provide this expertise because they put the money into the testing that produces this expertise.

Perhaps the most compelling reason for supporting data compensation is that it is the farmer's insurance policy against losing valuable production tools. In an age when many of the older agricultural chemicals are developing resistance problems or are being scrutinized for possible environmental or safety problems, it is more important now than ever to have research companies investing millions of dollars in the development of unique new chemical entities. These new products of the future are expected to be more specific to my needs with fewer environmental effects.

To me, these products represent a productive future in agriculture, with higher expected crop yields, while at the same time, requiring the use of less product per acre and farming methods that will protect our soil.

Today's consumers are questioning historic agricultural practices, including the use of pesticides. It strikes me as strange that Congress would consider eliminating data compensation since this would obviously foster the proliferation of more of the older chemicals and discourage the development of new and safer products.

Please, in your Senate Committee action in S.1516, preserye data compensation as it exists in the present law and do not discourage research and development incentives which promise farmers innovative products and maximum economic yield per acre.

NATIONAL ARBORIST ASSOCIATION INC.

ROBERT FELIX
Executive Vice President

174 Route 101
Bedford Station - Box 238
Bedford, New Hampshire 03102
(603) 472-2255

August 13, 1987

Senator Patrick J. Leahy, Chairman
Committee on Agriculture, Nutrition and Forestry
Russell Building, Room 328A
Washington, DC 20510-6000

Subject: S.1516 - FIFRA

Dear Chairman Leahy,

The National Arborist Association is a trade association of commercial tree service firms spanning the United States. Our 650 member firms, employing more than 40,000 people, care for the trees of America's urban forests on residential, commercial, institutional and municipal properties. These are the landscape plants that represent as much as 20% of the value of any real estate, provide us with the oxygen we need to breathe, filter and cool the air and beautify our environment. In the course of daily operations we have the need to apply pesticides to trees and shrubs in order to control destructive insects and diseases.

Our interest in any amendments to FIFRA center around the urban commercial pesticide applicator. It is our belief that the existing FIFRA does not adequately address certification and training requirements for commercial applicators. Technology has improved in terms of pesticides available and pesticide application techniques. As a result, in the landscape industry few, if any, restricted pesticides are used. In most states this allows for the application of most pesticides (general use) by un-regulated personnel, not necessarily under the supervision of a Certified Commercial Applicator.

We would urge the Committee to strengthen existing requirements for certified commercial applicators and to give EPA the legislative authority to require that all other commercial applicators have verifiable training and be registered through the state lead agencies. Such action would serve several purposes:

NATIONAL ARBORIST ASSOCIATION, INC.

1. Only personnel meeting standard training requirements would be applying pesticides, general use or restricted use.

2. Such training requirements, through the recertification process or a re-registration process, could be updated as may be needed and there would be a certainty that all applicators are aware of the latest information available.

3. Registration would give the state lead agencies an audit trail on all commercial applicators. Those who violate regulations could be indentified and suspended. Presently, in most states, there is no audit trail on a commercial applicator using general use pesticides.

The urban pesticide applicator industry is committed to improved training and supervision of field personnel applying pesticides. The tree care industry has demonstrated this via our multitude of applicator training programs.

We support the proposed amendment to Section 4 (7 U.S.C. 136b) found in S.1516, particularly the concept of the Registered Commercial Applicator. Although this seemingly imposes more stringent requirements on industry, we would welcome such a mandate as it supports the concept that industry has been trying to impose on practitioners for some years.

However, we take exception to the proposed amendment to Section 6 (f)2, Request for Hearing to allow any person "(including a person without an economic interest in such pesticide)" as this only serves to dilute and obstruct the process. We object to 3(c)(8)(F) for the same reason.

Thank you for considering our position in this matter.

Respectfully submitted,

NATIONAL ARBORIST ASSOCIATION

Robert Felix
Executive Vice President

RF/nrg

TESTIMONY BY HARLEY JOHNSON

JOHNSON CHEMICAL COMPANY

OSAGE, IOWA

Before The Senate Agriclture Committee

Mr. Chairman, my name is Harley Johnson, Johnson Chemical Company, in Osage, Iowa. I am a pesticide dealer at an agri-center which supplies herbicides and insecticides to corn and soybean farmers. I have been in business for over 20 years and consider my business a typical "mom and pop" operation. I have also farmed for myself.

I wish to be on record as supporting data compensation as it exists in the 1978 amendments to FIFRA.

In my business my primary concern is farmers and their needs. Farmers need a much higher quality of service and technical assistance which will give them a competitive edge and potential profits. I operate as a distribution agent. I think I'm in a pretty good position to tell you what farmers are asking for. At the agri-center we offer a combined package of products and services, in addition to sales and service such as training aids and seminars, direct product inquiry and customer profile data.

Traditional ways to get input to growers are no longer efficient and will change. Farmers need to be able to buy guaranteed total weed control or insect control at a preset cost agreed to pre-season. The proliferation of rules and regulations, licensing, restricted use of chemicals, and increasing paperwork all will increase the value of knowledgeable dealers to his growers.

A farmer may choose to use a generic pesticide, but most of the time he wants more than the product itself--he wants service after the sale. These supporting services can only be provided as the result of extraordinarily expensive research by the basic manufacturers. The encouragement of generic producers through the omission of data compensation would disrupt an orderly market which provides essential products and technical support to farmers. The loss of data compensation is a threat to the U.S. agriculture.

At the dealer level, the loss of data compensation and the weakening of the basic research companies will lower competition through the loss of small "mom and pop" distributors in favor of the larger, multi-state, non-researched based, distributors.

Basic manufacturers invest millions of dollars in our university system, testing and resolving scientific issues that arise on their compounds. Technical suppport and handling of customer complaints would deteriorate at the manufacturer, distributor and dealership levels as the research companies are weakened.

Dealers believe that growers purchase agricultural chemicals based on their recommendations. Consequently, dealers are concerned that their customers receive adequate support from research companies. When problems arise, dealers want the research companies to intervene and correct the situation.

Basic manufacturers maintain large technical staffs, including biologists, toxicologists, physicians and chemists. They provide analytical standards to regulatory agencies. They have hot lines that handle pesticide emergencies, even for generic brands. They have teams that respond to accidental spills. They have scientists that provide technical support for groundwater monitoring or residue analyses. Generic manufacturers generally provide no technical support.

Mr. Chairman, I understand that the above support costs millions of dollars to provide and is not recouped quickly. It will hurt my small company to send a signal to the research companies that they shouldn't invest in research; and it will disrupt the current distribution and service process that is important to farmers.

I urge you to preserve the data compensation system as it exists.

July 28, 1987

Commission on Agriculture, Nutrition & Forestry
United States Senate
Attn: Senator Patrick Leahy
Room 328A
Russell Senate Office Building
Washington, D. C. 20510-6000

Dear Senator Leahy:

The discussion concerning the compensation for research data pursuant to the registration of generic pesticides is a major concern to Iowa Agriculture. The money that the initial registrant expended was to insure that the pesticide was safe: environmentally, ecologically and toxicologically. Efficacy data could be developed without the major expenditures that the "safety" data requires. To allow manufacturers to begin marketing a product, once off patent, without fair and equitable compensation to the primary registrant would be unfair. Further, as the toxicological registration requirements change, and as new environmental issues develop (i.e. groundwater contamination), research on generic products will be needed. The initial registrant will likely establish this data while the manufacturers of "generics" will not. As the continuance of research is critical, I recommend that any registrant be required to compensate for the cost of the data.

Relative to questions about service to the customer: I do not believe that this issue is pertinent to the need to compensate for the use of research and registration data. Whether a generic manufacturer offers service to pesticide users or not is a business decision. The pesticide users can decide whether product service is necessary. However, I do not see generic manufacturers saving the farmer money. The cost of pesticides is minimal relative to the benefits they provide. Further, the price for those pesticides which have gone off patent have generally been reduced almost to the cost of production.

I am extremely concerned that research continue thus insuring the safe use of pesticides which are necessary for economically efficient agricultural production. Compensation for registration data is critical to this end. Please do not hesitate to contact me if I may be of service and answer other questions about these issues.

Sincerely,

M. D. K. Owen
Associate Professor and
Extension Weed Science

MDKO:skf

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STATEMENT OF THE INTERNATIONAL SANITARY SUPPLY ASSOCIATION
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
U.S. SENATE

JULY 30, 1987

Mr. Chairman, my name is Jack Ramaley. I am President of the International Sanitary Supply (ISSA). We appreciate the opportunity to submit this statement as part of the official hearing record for the Senate Committee on Agriculture, Nutrition and Forestry and to comment on S. 1516 and other amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). We commend this committee for its continued leadership on important pesticide issues.

The International Sanitary Supply Association (ISSA) is a voluntary non-profit membership association consisting of about 3,200 companies located in every state that are engaged in the manufacture, formulation, distribution and sale of antimicrobial and general cleaning and maintenance products for institutional establishments such as hospitals, schools, restaurants and hotels as well as industrial uses. A significant number of these products are utilized to protect public health and safety and are, therefore, regulated as "pesticides" under FIFRA.

We at ISSA would like to comment briefly on two aspects of S. 1516--A) reregistration fees and B) certification and training requirements and on three additional pesticide concerns that are not included in S. 1516--C) provisions of H.R. 2869 to coordinate and synchronize data requirements between the state and EPA, D) a fast track registration system for "me-too" products and label changes and E) preventing local political jurisdictions from regulating the sale and use of pesticides.

ISSA Comments on S. 1516:

Although we have had limited time to review and analyze S. 1516 and have not had an opportunity to obtain a complete review by our membership, we would like to offer some comments on S. 1516 and would appreciate an opportunity to submit a supplemental statement at a later time to comment on some of the additional provisions of this proposed revision of FIFRA.

A) REREGISTRATION FEES:

We at ISSA are strongly opposed to the reregistration fee proposal contained in S. 1516. Such a fee proposal would increase by five times the fees contained in H.R. 2482 and S. 2792 (99th Congress) or included in H.R. 2463, introduced this year, and contains none of the waivers and exemptions important to small businesses and producers and distributors of antimicrobial products.

The International Sanitary Supply Association is composed of primarily small businesses (65 percent of which have sales under $2 million). These businesses would be disproportionately affected by the proposal in S. 1516 to establish reregistration fees. This segment of the industry holds numerous pesticide registrations and is largely populated by small formulators who have their own registrations or who are subregistrants. Many of these formulators produce a wide variety of low-volume, low profit products that could not withstand these proposed substantial reregistration fees.

Small antimicrobial pesticide producers would be adversely affected by this proposal to establish reregistration fees. Many small producers hold multiple registrations and produce private label products. Any FIFRA amendment that arbitrarily establishes a fee based on the number of registrations, rather than on volume sold, disproportionately affects formulators and small businesses.

When these proposed reregistration fees are combined with other fees, such as those at the state level, the cumulative effect is devastating for small businesses. The reregistration provision of S. 1516 is financially stifling and affects every ISSA member company. Because of this factor, as well as for other reasons elaborated below, we at the International Sanitary Supply Association respectfully request that the Senate Committee on Agriculture, Nutrition and Forestry drop the fee proposal included in S. 1516.

1) REREGISTRATION FEES, USER FEES AND THE PUBLIC INTEREST:

User fees should be limited to specific cases where a special benefit is derived by a private party. For example, visitors to national parks have paid an entrance fee to help defray the upkeep of the park and its facilities. Boaters have paid fees for use of canals and the inland waterways. Farmers and cattlemen have paid user fees for grazing on public lands throughout the West. Fees for the provision of licenses to operate in such federally regulated areas as the broadcasting, nuclear power and petroleum industries have been approved. Each of these individuals, organizations or companies has derived specific levels of benefits by utilizing government facilities. The statutes, however, empowering federal agencies to regulate these industries, are to be distinguished from FIFRA, FFDCA and TSCA.

These three statues require across-the-board pre-clearance of a specific commerical product--drugs, pesticides and toxic substances prior to manufacture, sale and distribution. In each case, the federal government acts as a clearinghouse, collecting and evaluating scientific data, and ultimately registering pesticides and approving these products for public use. This further ensures that such products do not present an unreasonable risk to man or environment, thereby providing a distinct benefit to society in general, a function conspicuously absent from the activities of other federal regulatory bodies. Therefore, the registration, reregistration and pre-clearnance of products broadly benefits the general public in a manner unique to the pesticide, toxic substances and drug industries.

With respect to pesticides, these products and their uses clearly provide a public benefit, enhancing our quality of life, stimulating new food production and protecting public health and safety. Therefore, the imposition of a reregistration fee under such circumstances is, in fact, a tax. Pesticides, including antimicrobial products, should not be singled out for special user fees when other pre-clearance statutes, such as those for drugs and toxic substances, do not contain any provisions for user fees, registration or reregistration fees.

Any system of reregistration fees would, in effect, result in taxing a few to finance a regulatory system that benefits many. When government services benefit society generally, the expense of those services should be borne by the taxpayer at large, not by individuals.

The reregistration fee is actually an attempt to impose a new tax on pesticide producers, a tax that will increase the cost of production and drive up the cost of pesticide products, including antimicrobial products.

The primary purpose of requiring reregistration of pesticides is to protect the public health and safety. Thus, the EPA reregistration process benefits the general public and the American taxpayer. These reregistration costs should be paid with public funds, not special reregistration fees.

If the purpose of FIFRA is to protect the public's health and safety and the environment and to broadly serve the public interest, we should not impose reregistration fees on pesticides.

2) THE REREGISTRATION FEE SYSTEM IN S. 1516 WILL HAVE AN ADVERSE ECONOMIC IMPACT ON THE ANTIMICROBIAL PORTION OF THE PESTICIDE INDUSTRY:

We would respectfully urge the committee to evaluate the economic impact that such a reregistration fee would have on pesticide producers and formulators that produce antimicrobial products for institutional and industrial uses.

We believe that the reregistration fees in S. 1516 will have a devastating impact on every portion of the antimicrobial industry. Importantly, it will affect distributors and downstream users of antimicrobial products, such as hospitals, schools, restaurants, hotels and other institutional/industrial facilities.

Many antimicrobial producers manufacture products that have a very specialized or limited use and, therefore, are frequently produced in low volumes. Many of these antimicrobial products are manufactured in batches of 10,000 to 50,000 pounds, and sell for $1 per pound.

The specialty market in antimicrobial products has been successful because small formulators have been able to produce minimum quantities of antimicrobial products for limited uses, sometimes perhaps just for a couple of drums.

To illustrate, most ISSA formulators produce private label products for distributors. As a consequence, one EPA registered formulation is sold to numerous distributors under as many different labels, each requiring a supplementary registration.

Because of the extremely competitive nature of the antimicrobial industry, many formulators maintain "backup" registrations. "Backup" registrations are current EPA registered products not actively sold on the market. In the event that an actively marketed EPA registered product is cancelled, a "backup" registration can be immediately introduced into the marketplace. As such, "backup" registrations allow formulators to continuously provide a specialized product for a particular need, an essential element in maintaining a firm's competitive edge.

One company maintains 30 EPA registered products, 20 of which are not actively marketed. Another formulator maintains over 500 registrations, 150 of them which are dormant. Because these "backup" registrations do not generate revenue, the imposition of reregistration fees for such registrations will force formulators to cancel these "backup" products. Such a course of action will result in a potential loss of market share and damage their ability to effectively compete.

With respect to the development of new antimicrobial products, an enormous reregistration fee would have a severely detrimental impact because innovative companies could not recoup the costs of such a fee from the sales volume of the chemical. Thus, new disinfectant chemicals that are so important to preserving public health and sanitation would not be developed. This fact is easily confirmed when one looks at the other costs incurred such as testing and marketing in the development of new chemicals. The combined cost factors will discourage or prohibit the development of new products which, in turn, could have a long-term adverse impact on public health in this country.

Of the nearly 300 registered antimicrobial products, less than two dozen are produced in quantities of over one million pounds, at an average cost of $1 to $2 per pound. We know of no registered antimicrobial product that generates more than $10 million in sales.

According to the definitions of S. 1516, most registered antimicrobial products would require a $100,000 reregistration fee, since most are contained in pesticides registered before 1978 and sell less than $10 million in gross sales. Only a handful of the registered antimicrobial products fall into the $10,000 per year or $50,000 class that were included in pesticides registered after 1978.

S. 1516 does not contain any waivers, exemptions or adjustments to the reregistration fees for antimicrobial products. There are no waivers or exemptions for low volume, low profit products. Most antimicrobial products generate minimal profits at best. Conversely, some agricultural pesticides sell for $5 to $15 per pound of active ingredient and sell more than 100 million pounds, generating sales of $500 million to $700 million. It is grossly unfair to group agricultural and nonagricultural products under the same reregistration fee structure because of the inherent differences in sales and profit margin.

A reregistration fee structure that arbitrarily imposes costs of $100,000 and $50,000 per antimicrobial would have a devastating economic impact on the antimicrobial pesticide industry.

First, of all the nearly 300 presently registered antimicrobials, only a handful would survive such fees. We frankly believe that hundreds, even thousands, of products will be dropped from the market. Second, the public health could be jeopardized as a result. Because the products are used in schools, hospitals, food establishments ranging from restaurants to food processors, hotels and other instutitional/industrial establishments, the public health and sanitary needs may be negatively affected. Third, the competition that now exists between hundreds of products and dozens of companies will cease to exist. Only a handful of products and companies would be left to divide up the market. Fourth, product selection, with widespread choice, would cease to be an alternative. Fifth, research and development would almost disappear since few products could afford such huge reregistration fees. Sixth, the prospects for economic dislocation, job losses, job replacements, job retraining and localized plant closings are staggering. Seventh, such fees would effectively destroy the antimicrobial industry, as we know it today, and would result in the elimination of many small businesses across the nation.

In effect, the reregistration fees in S. 1516 will not raise sufficient funds to run the program, simply because they cannot be collected. If only 10 products survive (and some industry leaders have suggested that only three or four may continue to exist), and each pays $100,000 ($20,00 in each of five years), the total revenue will be about $1 million. From a starting total of about 300 antimicrobial products, we would raise only a minimal amount. If EPA accountants are hoping to raise $10 million to $30 million (out of a total of $113 million) from antimicrobial products, they are suffering from a severe case of wishful thinking, based on unrealistic economic estimates.

3) REREGISTRATION FEES ARE PART OF AN EXPANDING SET OF COST FACTORS:

It is important to note that the proposed reregistration fee system is but one of an already expanding fee structure estabished at the state level. It costs about $1500 for each registered pesticide product to be sold in every state. California has just recently raised its registration fee to $200 per product per year. Connecticut has a mandatory five year registration system and requires a $200 up front payment for each product. Wisconsin has established a $4,000 fee for the registration of active ingredients, and uses part of these funds to pay for a groundwater program. Iowa has just adopted its own groundwater-pesticide program. Some states require a minimum of two years continued registration for a discontinued item, such as Indiana. Since every pesticide must also be registered in each state before it can be sold there, pesticide producers find themselves faced with an already escalating financial burden.

A recent survey of state legislatures across the country indicates that several states are requesting new state fees for pesticide registration or are seeking to broaden the pesticide registration system to fund other programs. These trends will continue into the foreseeable future, further increasing the cost of marketing a pesticide on a nationwide basis.

The federal regulatory process has resulted in increased financial burdens on manufacturers, formulators and distributors. The Agency will frequently request that the registrants amend their label or comply with a new registration standard or change a product classification to "restricted use." It has become common for EPA to require labeling changes or amendments on many products on an annual basis to address such issues as farmworker safety, groundwater protection, storage and disposal. The pesticide industry is currently incurring tremendous costs from these required changes by having to submit amended labels, prepare new product art work, destroy obsolete label inventories order small, uneconomical label quantities and, in some cases, re-labelling existing stocks.

The costs of any registration fee system must be placed in the context of other EPA programs that affect the pesticide industry. Within the last two years, the Agency has begun a new data call-in for the purpose of reregistering agricultural products; this program is under way. In addition, the Agency has recently issued a data call-in on about 300 antimicrobial products. Some will need little or no data, but data on more than 250 is being called in. Although the Agency has been cognizant of the economic burdens that such a call-in might impose on the antimicrobial industry, the data call-in will force many antimicrobial producers to re-evaluate the continued maintenance of registrations for low volume, low profit products.

If a new reregistration fee of $50,00 or $100,000 is added to the already burdensome costs of new testing (especially for the development of exposure data), many of these products or active ingredients are going to disappear from the marketplace.

4) SMALL BUSINESS CONSIDERATIONS:

S. 1516 does not grant waivers, exemptions or adjustments to reregistration fees based upon public interest and economic hardships for small businesses, nor does it consider firm size, pesticide sales, or the number of registrations with EPA.

Small businesses are particularly concerned that the adoption of a reregistration fee schedule for antimicrobial products discourages innovation, will limit the number of products available to the distributor and the consumer and will reduce the number of registrations that a pesticide producer could afford to carry in its product line.

Unless some exemptions or "caps" are created for small businesses, reregistration fees would have a devastating economic impact on small firms. We would like to make the following suggestions:

First, the language contained in S. 2792 or H.R. 2482, (99th Congress) or H.R. 2463 (100th Congress) dealing with reregistration fees, specifically contains language that would have allowed the agency to collect data on volume of sales and distribution of market share so that EPA could determine a company's market share.

Second, we urge that this committee accept the Small Business Administration's definition of a small business; i.e., a business of 500 employees or less (for the chemical industry). Third, we would respectfully urge the committee to adopt a suggestion by the Small Business Administration that fees charged to small businesses for whatever reason should be no more than 1 percent of the annual gross requested. This small business cap on fees parallels the language of both House and Senate bills, H.R. 2482 and S. 2792, and would establish a consistent tiered formula for small businesses. Fourth, since no agency can predict in advance the annual gross revenues for a pesticide product, we suggest that such fees be based on the sales of the first two years, and that collection of the fees be delayed until the beginning of the third year. This delayed payment would, we believe, actually result in more fees being collected.

In fact, in 1986, Congress passed several small business provisions in H.R. 2482 and S. 2792, that established a very limited fee structure for active ingredients undergoing reregistration. These bills would have: 1) established a fee structure for agricultural and non-agricultural active ingredient pesticides, 2) created a waiver or reduction of such fees for non-agricultural minor uses or for products where the "value or volume of use...is small," 3) established a waiver or reduction for antimicrobial products where the active ingredient did not exceed 1 million pounds per year of production, 4) devised a fee cap for small businesses based on the sales of the active ingredients and 5) apportioned these fees according to a company's share of the market. In addition, the Congress included a specific definition of antimicrobial products. Congress was clearly evaluating these potential reregistration fees and reduced fees for non-agricultural pesticides and antimicrobial products.

Although we strongly favor a small business waiver or formulator's exemption, our support for this potential waiver should not be interpreted as support for the establishment of a reregistration fee system. ISSA believes that this fee proposal is unadvisable, irrespective of any proffered waiver provisions.

Manufacturers, formulators and distributors that market antimicrobial produces used in institutional and industrial settings are united in their opposition to this proposed reregistration fee schedule. We again urge this committee to reject the fee contained in S. 1516.

B) COMMERCIAL APPLICATORS, CERTIFICATION AND TRAINING AND ANTIMICROBIAL PRODUCTS:

We at ISSA are concerned that sections 101 and 401 of S. 1516 are so loosely designed as to require cleaning and maintenance workers who apply antimicrobial products to be trained and certified as commercial applicators under FIFRA.

We believe it is neither fair nor necessary for cleaning and maintenance personnel to be trained to apply non-restricted use antimicrobial or consumer products.

During the last three years, Congress has discussed the advisability of extending the training and certification requirements from those who apply restricted use pesticides to those who apply non-restricted use (general use products) pesticides.

Under the definition of Section 101 of Title I of S. 1516, the bill defines a commercial applicator as a person who "uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the business or work of the person."

We believe that there are several inherent problems with this definition, including:

1) "any pesticide" includes all restricted and non-restricted pesticides and does not draw any distinctions between pesticides. Disinfectants, sanitizers and household bug sprays are all lumped together with restricted use agricultural products. We believe that there ought to be an exemption for antimicrobial products and consumer products.

2) "any person...for hire" might well include maids, janitors, cleaning personnel, building maintenance people, apartment managers and maintenance personnel, hotel and restaurant people who sanitize everything from floors to dishes, and hospital and school personnel who clean facilities at institutional settings. Do these people need to have special training and must they be certified as commercial applicators? Should a janitor who cleans restrooms and scrubs toilets be specially trained if he is applying a common, general use pesticide that is purchased in grocery stores and hardware stores, and otherwise available to the general public? Should a maid or cleaning service personnel be specifically trained if the homeowner can apply these same pesticides without training? It makes no sense to restrict the employees of the homeowner when the homeowner is simply required to follow the label instructions in applying the pesticide.

3) This provision--2 (e) (1) (A) (ii)--provides that the Administrator may determine if a product could be "applied without the need for training." No administrative procedures are established, thus thousands of companies with thousands of prouducts each might need to apply to the Administrator to seek an exemption from training. We are potentially setting up a system in which the Administrator must make a determination on each pesticide. Such a process is an unnecessary, costly, bureaucratic disaster that will be burdensome to both the Agency and the industry, especially small businesses. It will not achieve the purposes for which it was designed, and will create costly economic disincentives and paperwork burdens. We do, however, support the language of (ii) when it limits the coverage to persons who use or supervise the use of a pesticide "for hire as the principal part of the business or work of the person." It should not be revised to read: "as a principal part of the business or work of the person." The word "the" implies a major part, whereas "a" principal part is vague and ambiguous, and could be interpreted to include literally millions of people who apply antimicrobial and consumer products. We strongly urge the retention of the term "the principal part."

Specifically, we at ISSA would recommend that section 2 (e) (1) (A) (ii) (page 5 of S. 1516) be amended to read as follows:

> "(ii) uses or supervises the use of any pesticide, except for non-restricted use for an antimicrobial or consumer products (or other pesticides that the Administrator determines may be applied without the need for training), for hire as the principal part of the business or work of the person; or"...

We also believe that certification and training provisions of section 401 should also be changed to specifically exempt from training any commerical applicator who uses an antimicrobial or consumer product.

We respectfully recommend that section 401 (a) be altered so that a new paragraph (C) could be added to subsection (d) (1) to read as follows:

> 4 (d) (1) (C) "Exception-Such certification and training shall not apply to a commercial applicator who uses or supervises the use of non-restricted use antimicrobial or consumer products"...

We believe the provisions of section 101 and 401 need to be clarified so that antimicrobial and consumer products are exempted from needless coverage under the certification and training of pesticide applicators and are not designated as pesticides applied by commerical applicators.

C) COORDINATION AND SYCHRONIZATION OF PESTICIDE DATA REQUIREMENTS AMONG STATES AND EPA:

We at CPDA strongly support H.R. 2869, the Pesticide Data Coordination and Sychronization Act of 1987, introduced by Congressmen Steve Gunderson (R-Wisc.) and Pat Roberts (R-Kan.).

In 1984, California passed S.B. 950, to require the filling of pesticide data gaps. To implement this law, the state adopted a definition of a "data gap," created a list of tests that need to be completed, and established a detailed timetable for filling these data gaps. The state, however, did not take into consideration the attempt of the Congress to create their own reregistration timetables in H.R. 2482 and S. 2742 (99th Congress) or H.R. 2463 (100th Congress) to fill these same data gaps.

"In essence," remarked Steve Gunderson (R-Wisc.) (Congressional Record, July 1, 1987, E 2740), "in attempting to establish their own expedited reregistration programs to fill data gaps, the states actually establish agendas and timetables which will duplicate and even conflict with the federal requirements."

"...It is critical," concluded Gunderson, "that data requirements among the states and EPA be coordinated and sychronized so that only one set of data needs to be generated within the same timeframe." "Unnecessary, repetitive and redundant testing only consumes valuable time and resources, but also delays the closing of data gaps," he noted. "Valuable time and resources which could be used to develop new data are wasted in focusing on gaps that have already been or are in the process of being filled."

"Unrealistic timetables for implementing and generated these needed studies could cause some of these products to be dropped from the market," concluded Congressman Gunderson, "especially many low volume, low profit specialty products, including antimicrobial products..."

H.R. 2869 will help reduce the cost of pesticides, eliminate duplicative and unnecessary testing, expedite the closing of data gaps and make sure that pesticides for consumers, especially antimicrobial products, will be available wherever needed.

D) FAST TRACK REGISTRATION FOR "ME-TOO" PRODUCTS AND LABEL CHANGES:

We at ISSA face a difficult problem in obtaining "me-too" registrations or simple amendments to existing registrations. We are not talking about new chemicals, new uses or new efforts by the EPA to review and analyze new toxicological data. We are, however, talking about unreasonable delays in the registration process at EPA (Registration Division).

Many of these applications or amendments sit in the Registration Division of EPA in excess of a year or more. In many cases, the processing of these items could take only an hour or certainly less than a day, if the Registration Division people would process them in an expedited and timely manner. Although the backlog is not as large as it was in 1975-1977, it is clearly the largest backlog in a decade and threatens to get worse, unless Congress takes decisive action.

This unnecessary backlog exists because the Registration Division at EPA is giving priority to new chemicals and new uses of existing chemicals while placing "me-too" registrations, products similar or identical to those already marketed, and label changes on a low priority. These applications simple languish at EPA and are not being processed in a timely manner.

Some of these labels provide new information on how to use the product more safely or a more detailed warning. The antimicrobial industry has literally thousands of labels, more than any other segment of the pesticide industry and is therefore disproportionately affected by the Agency's inability to process label changes.

The unnecessary backlog of "me-too" registrations at EPA has an obvious economic impact on pesticide manufacturers and users. First, absent such processing by EPA, a company is denied entry into the marketplace and competition in the pesticide industry is stifled. Second, pesticide consumers are frequently denied the opportunity of purchasing lower priced pesticides. Third, huge delays at EPA prevent manufacturers from planning their sales and marketing efforts and results in some products missing their season. The impact is greatest on small companies with a limited assortment of products. Smaller manufacturers, formulators and distributors don't have the recourses to "ride out" long EPA delays.

Small antimicrobial pesticide products could be adversely affected by delays in the registration process. Many small producers hold multiple registrations and produce private label products for distributors. As a consequence, one EPA registered formulation is sold to numerous distributors under as many different labels, each requiring a supplementary registration. For example, one formulator maintains approximately 350 registrations and holds as many as 200 supplementary registrations for each individual registration or a total of 70,000 products and labels. The delays for a simple label change can have a significant ripple effect for the antimicrobial producers and distributors.

We believe that it is not the intent of the Senate Committee on Agriculture, Nutrition and Forestry to foster this unnecessary backlog at EPA and its disastrous economic effects.

We believe that the EPA needs to redirect its priorities to expedite the processing of "me-too" applications and amendments to existing registrations and needs Congressional direction to accomplish this change. The Agency needs to re-establish its priorities to properly process these registrations within specifically defineable timetables. As part of its reassessment of the present registration system, the Agency should assign some of its registration personnel to the administration of the whole registration process, including me-too registrations and amendments. If necessary, the administration should be directed to transfer personnel from other programs so as to ensure that pesticides are timely registered.

We at CPDA favor an amendment to Section 3 (c) (3) that would require the Administrator to:

1) Achieve the registration of all pesticides in the most expeditious manner practicable;

2) Establish a registration priority to applications for a product that is identical or substantially similar in composition to any currently registered pesticide or for an amendment to existing registrations;

3) Notify the registrants within 45 days after receiving an application to determine if it is complete;

4) Notify the registrants within 90 days after receiving a completed application if it has been granted or denied; and

5) Notify the registants in written form of the specific reasons for denial of registration.

We at ISSA would like to suggest an amendment to accomplish this reordering of EPA's priorities and have attached it for your review. We join with CPDA and CSMA in endorsing this fast track registration for me too products and label changes and respectfully urge the Senate Committee on Agriculture, Forestry and Nutrition to adopt it as part of its overall FIFRA amendments for 1987.

E) STATE POLITICAL SUBDIVISIONS SHOULD NOT REGULATE SALE AND USE OF PESTICIDES:

We at ISSA strongly oppose S. 1524, the Authority of Local Governments Under FIFRA, introduced by Senators John Chafee (R-R.I.), David Durenberger (R-Minn.) and Robert Stafford (R-Ver.) on July 22, 1987. We support the decision of the U.S.

Court of Appeals for the Fourth Circuit when it ruled on June 16, 1987, in the case of the Maryland Pest Control Association versus Montgomery County, Maryland, that FIFRA preempts and invalidates local action to regulate the sale and use of pesticides. We respectfully urge that S. 1524 not be included in any package of FIFRA amendments considered by this Committee.

Under Section 24 (A) of FIFRA, Congress extended limited pesticide authority to the states to regulate the sale and use of pesticides. The legislative history clearly demonstrates that Congress did not want the State to share its authority with local jurisdictions.

When the Senate Committee on Agriculture passed the FIFRA bill in 1972, its accompanying committee report included:

> The Senate Agriculture Committee considered the decision by the House Committee to deprive political subdivisons of states and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty states and the federal government provides sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any local authorities, whether towns, counties, villages or municipalities, have the financial wherewithal to provide necessary expert regulation comparable with that provided by the state and federal governments. On that basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the states, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, P. 4008 (1972).

At about the same time, the Senate specifically rejected an amendment that would have allowed local political subdivisions, such as cities, towns, counties, etc. to regulate the sale and use of pesticides. The vote was 71-0.

Despite this explicit legislative history, there have been, during the 1980s, many political subdivisions of a state that have attempted to exercise regulatory authority.

Local jurisdictions have been enacting restrictions on pesticides that create considerable hardships on farmers, ranchers, foresters, homeowners, pesticide users and manufacturers. These jurisdictions are, in effect, denying the pesticide user--and the public--the benefits of pest control.

We oppose granting local political subdivisions the authority to regulate the sale and use of pesticides for the following reasons: First, local jurisdictions simply are not equipped to make the scientific and regulatory decisions required to validly regulate pesticides. When regulations are based on fear, hysteria and other unscientific grounds, the resulting loss of benefits is unwarranted. Second, we question the need for local jurisdictions to regulate pesticides. What risk uncontemplated by EPA or the State Agency does the local community want to protect against? What risk uncontemplated by EPA or the State Agency does the local community want to protect against? What risk goes unprotected except for local notification ordinances? And what is the magnitude of that risk? Have EPA and the states been negligent in not identifying and reducing this risk? Third, we believe that the legislative history is clearly written to explicitly reject local regulation of pesticides. Fourth, we oppose local jurisdictions regulating the notification of use of pesticides in both urban and rural settings. These regulations should be established at the state level.

Notification can take many forms. One county in a New England state contemplated a "notification" regulation which would have required persons dusting their roses to notify everyone within a half of a mile before doing so. Does notification include prior notification, post notification, personal notification, or notification by publication? Then the question arises as to who is to be notified: those immediately adjacent or everyone within a certain radius? Consider, for example, an apartment dweller wishing to spray for any common pest; who must that person notify?

The broad definition of pesticide adds to the potential breadth and confusion. It could require people to post a notice if they sprayed for household insects, applied a disinfectant in the bathroom, dusted roses, or put chlorine in a swimming pool. Commercial establishments using cleansers and other cleaning solvents which are pesticides might need to post continuously.

We at ISSA favor an amendment to Section 24 (a) of FIFRA to prevent local jurisdictions from regulating the sale and use of pesticides. With this amendment included, Section 24 (a) would read as follows: "A State, but no political subdivision of a state may regulate the sale and use of any federally registered pesticide..."

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COMMENTS

SUBMITTED BY

ELLEN HAAS

EXECUTIVE DIRECTOR

ON BEHALF OF PUBLIC VOICE FOR FOOD AND HEALTH POLICY

CONCERNING REAUTHORIZATION OF

THE FEDERAL INSECTICIDE, FUNGICIDE AND

RODENTICIDE ACT AND S. 1516

BEFORE THE

SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

AUGUST 12, 1987

Public Voice for Food and Health Policy, is a non-profit consumer research, education and advocacy organization that works to advance the consumer interest in food, nutrition and agriculture policymaking. We are pleased to submit these comments to provide you with our thoughts on reform of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)--a law in dire need of revisions to strengthen public protections from residues of inadequately tested and potentially dangerous pesticides.

The National Academy of Science's recent report, Regulating Pesticides in Food, confirms our worst suspicions. The report discloses that significant risks of cancer to humans are presented by commonplace pesticides in many popular foods. Tomatoes, beef, potatoes, oranges, lettuce, apples, peaches and pork were named by the scientific panel as the eight foods posing the greatest health risks from pesticide residues.

The report found that 90 percent of all fungicides, 60 percent of all herbicides and 30 percent of all insecticides used cause or potentially cause tumors. The report does not even paint a complete picture of the health threats. The scientific panel which wrote the report did not consider whether any of the 28 pesticides that were reviewed cause birth defects or mutations.

We believe the NAS report strongly indicts the Environmental Protection Agency (EPA) for failing to protect the public from tumor-causing substances. It confirms that consumers have good reason for consistently naming pesticide residues as the number one food hazard.

And unless egregiously contaminated foods create acute illness--as in the 1985 incident of aldicarb contaminated watermelons in California which caused several hundred illnesses--pesticide residues are likely to remain undetected. According to recent General Accounting Office (GAO) reports (Pesticides:

Need to Enhance FDA's Ability to Protect the Public From Illegal Residues and Pesticides: Better Sampling and Enforcement Needed on Imported Food,) the Food and Drug Administration (FDA) conducts minimal and inadequate testing of pesticide residues. According to GAO, FDA samples represent less than two-tenths of one percent of domestic food production. And FDA even permits the sale of foods known to be contaminated. Because food can spoil before residue test outcomes are available, FDA has allowed, for example, the marketing of nearly 45% of contaminated imported produce.

Pesticide residues permeate the food supply as invisible, indelible dangers. Consumers who purchase food in the marketplace simply cannot protect themselves from harmful pesticides. Consumers have no easy way of identifying which pesticides have been used on their fruits and vegetables. Consumers cannot see, smell, or taste any lingering pesticide residues.

This makes it especially clear why consumers need stronger government involvement and stronger laws to ensure a food supply safe from harmful pesticide residues. FIFRA is the right place to start--because the law can preclude unsafe chemicals from ever entering the foodchain through deliberate application. We urge you to quickly pass FIFRA reforms to address pressing consumer safety problems.

The FIFRA legislation which passed the House and Senate last session in large part took giant strides forward toward improving our protection from pesticides. Public Voice was part of the coalition of environmental, consumer and labor organizations that negotiated with chemical interests to develop the compromise legislation. The legislation contained many essential elements that would have remedied notable weaknesses in the current regulatory program.

We believe the core of that legislation had crucial aspects that should form the foundation for FIFRA reform. These are the components of last year's compromise that we hope will be in the FIFRA bill Congress will pass:

o require the EPA to develop an efficient schedule for registration of pesticides with lists of priorities

o require data to support reregistration

o create a revenue pool from registrant fees to assist EPA in its reregistration program

o establish expeditious EPA review and regulatory action on registrations that are based on invalid or faulty data

o increase public access to health and safety data submitted by industry by permitting public perusal of such information prior to EPA action on registration

o provide increased EPA authority to regulate inert ingredients in pesticides o require EPA to take action against a pesticide when there is concrete evidence of harm

o prohibit the sale of imported foods which have pesticide residues that have been suspended, cancelled or withdrawn due to health risks

o prevent contamination of groundwater from pesticides.

Public Voice believes that S. 1516, introduced by Chairman Patrick Leahy and Senator Richard Lugar, is a positive step forward toward a meaningful federal pesticide law that adequately addresses public health needs. Its mandatory timetable for reregistration, and EPA safety evaluation of pesticides and inerts, penalties for false data and increased public access to data, are particularly important.

We join the National Resources Defense Council in supporting several amendments to make the legislation significantly more effective. These include: authorization for EPA recalls, ground water protection, citizen right-to-sue, worker protection, export controls, and stronger pesticide removal provisions.

There were two unacceptable amendments that were included in last year's House bill which we objected to, and still oppose. One involves state preemption: it would have eliminated states' power to set stricter limits for pesticide residues in food than those set by EPA. We strongly believe states have demonstrated an ability to react more quickly to public health risks from pesticides than the federal bureaucracy. For example, the move to ban EDB, a potent carcinogen, was initiated at the state level. Though states rarely set such limits, when they act, the public benefits. It is important for the public welfare that states' rights in this matter not be abrogated.

The bill that passed the House of Representatives on October 16th also included a provision that exempted pesticide applicators from liability for clean-up costs under all major federal environmental laws. We believe that such a provision is inequitable, would greatly jeopardize FIFRA reform and should not be included in FIFRA legislation.

The EPA estimates that 1 billion pounds of pesticides a year are used in domestic farming--that amounts to over four pounds of pesticides for each and every American. Many of these pesticides have either been inadequately tested or have actually been found to be hazardous. FIFRA reform is urgently needed to stop routine exposure of consumers, farmers and farmworkers to unhealthful pesticides. As Lewis Regenstein said in his book, America the Poisoned, "the ultimate victims of our pesticide folly are not the insects, but ourselves." We see this hearing as an important step to keep the process of FIFRA reform moving toward ultimate passage of a beneficial bill this session.

STATEMENT OF FARMLAND INDUSTRIES, INCORPORATED
BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

HEARINGS ON S. 1516
JULY 30, 1987

Mr. Chairman, my name is Robert R. Beeler. I am Director of the Chemical Operations Division of Farmland Industries, Inc. We thank you for the opportunity to discuss our position on the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA) and the need for changes in the current law relating to data compensation.

Farmland is an agricultural cooperative providing products and services to approximately 2,265 member local cooperative associations owned by over 500,000 farmers and ranchers in 19 states located in the Midwest and West. As a farmer-rancher owned cooperative, we are concerned about any issue which can directly or indirectly effect the ability of our owners to be competitive in the U.S. or world agricultural markets.

I am here today to testify on S. 1516, and to specifically focus on two provisions on this bill, data compensation under Section 3(c)(1)(D) of FIFRA and patent term restoration.

Mr. Chairman, we oppose the current language contained within the bill on data compensation. The approach suggested would not solve the existing problems with this section of the law but would only create more confusion. I would encourage the committee to consider the inclusion of S. 746, as introduced by Senators Kassebaum and Gore, which provides for reform in the current provisions of Section 3(c)(1)(D) of FIFRA concerning data compensation in S. 1516. The provisions of S. 746 would, at long last, place agricultural chemicals on the same basis as human drugs and the current Administration position for changes in the animal drug laws under the Federal Food, Drug and Cosmetic Act.

Agricultural chemicals, human drugs and animal drugs each require extensive testing to prove their safety and effectiveness followed by subsequent government approval prior to market introduction. However, only the pesticide law requires payment of compensation for data relied upon during the approval process which has been submitted by other parties. This requirement for data compensation acts as a disincentive for other manufacturers to enter the market.

The concept of data compensation was first introduced into FIFRA when the 1972 amendments were passed into law. Subsequent amendments to the data compensation provisions of the law were passed in both 1975 and 1978 both of which were intended to clarify these provisions. However, the system has still proved unworkable and inequitable for companies required to pay compensation.

The 1978 amendments to FIFRA made major changes which took the determination out of the hands of the EPA and placed it into arbitration between companies. This has proved to be extremely costly and time consuming.

Since the 1978 amendments to FIFRA were passed, only one case has been arbitrated. In that case, Stauffer vs. PPG Industries, the arbitrators provided for an award to Stauffer of 50% of its data costs plus an additional award of $0.15 per pound for each pound of active ingredient sold or used for a 10 year period. The total cost of the data in this case was approximately $3,000,000 but the total compensation awarded will amount to more than $15,000,000 based upon the arbitrators' own estimates.

One other case currently in arbitration, has found the original submitter of the data requesting 1/3 of the cost of the data from two separate parties plus $1.50 per pound for each pound of active ingredient sold or used during the first 5 years of marketing. It is interesting to note that one original party to this arbitation chose to cancel its labels and remove itself from the market since it could not afford the cost of the process and was fearful that if they received a decision similar to the Stauffer/PPG case they could not remain in business.

The point I want to stress here, Mr. Chairman, is that the process established by the 1978 amendments to FIFRA has a definite chilling effect on follow-on, generic production. There is a greater barrier to generic production than in the past. When there has been generic production in the past there has been a noticeable impact on the market.

In 1986 we looked at the effect of competition on the price of agricultural chemicals we distribute. When we looked at our historical sales record, we found that for three randomly selected chemicals that the price decreased an average of 18.1% when competition entered the market following patent expiration. At the same time, we found that for three other chemicals that had no generic competition that the price increased an average of 9.9%. If you consider that the products which had generic competition in the market could have increased their price by 9.9% the total savings to users was 28% in lower prices. Our results are shown in Table 1.

TABLE 1

PRODUCT TRADE NAME AND YEAR COMPETITION ENTERED MARKET

	Phostoxin (1982)	Treflan (1985)	Sutan (1984)
Pre-generic Price	30.20/kg.	28.50/gal.	19.89/gal.
Post-generic Price (1986 price)	24.28/kg.	21.43/gal.	17.90/gal.
Percent Change in Price	-19.6%	-24.8%	-10.0%
Average Price Decrease =	-18.1%		

PRODUCT TRADE NAME
(No Generic Competition)

Year	Furdan	Lasso	Lorsban
1983	40.72/gal.	17.73/gal.	26.80/gal.
1984	46.69/gal.	18.59/gal.	30.21/gal.
1985	44.82/gal.	18.61/gal.	29.59/gal.
1986	45.77/gal.	18.06/gal.	30.93/gal.
Percent Change in Price (1983-1986)	+12.4%	+1.9%	+15.4%
Average Price Increase -	+9.9%		

In general, prices usually decrease by approximately 20% when two or more manufacturers offer the same pesticide in the market. When you consider that USDA figures for 1985 show that a farmer's input cost for pesticides varied from 3.6% for burley tobacco to 35.7% for cotton grown in the southeast, a 20% reduction in pesticide prices could potentially make the difference between making a profit and losing money. Table 2 is an example of some of the pesticide input costs.

TABLE 2

	PESTICIDE INPUT COSTS	
CROP	1985 COST OF CHEMICALS PER ACRE 1/	1985 CHEMICAL PERCENTAGE OF CASH VARIABLE EXPENSE
Corn	$17.58	8.6%
Sorghum	8.52	13.4%
Barley	5.43	10.4%
Spring Wheat	5.09	12.5%
Durum Wheat	5.35	14.2%
White Wheat	9.85	12.9%
Winter Wheat	1.50	3.3%
Rice	26.88	10.8%
Soybeans	17.47	32.3%
Peanuts-all	79.63	29.3%
Cotton		
Delta	72.27	23.3%
Southeast	94.58	33.0%
Sugar cane		
Hawaii	125.64	4.8%
Tobacco 2/		
Burley	70.08	3.6%
Flu-Cured	94.44	4.6%

1/ Economic Indicators of the Farm Sector, Cost of Production, 1985 (United States Department of Agriculture, Economic Research Service, ECIFS 5-1).

2/ Annette Clausen, Economic Research Service, USDA

Another indicator of the effect of competition in the market can be found in the 1986 Industry Profile Survey prepared by the National Agricultural Chemicals Association. This information, the 1986 sales of pesticides in the United States, are shown in Table 3.

TABLE 3

	PROPRIETARY PESTICIDES	NON-PROPRIETARY PESTICIDES
Sales Dollars (millions)	2,679.1	1,320.0
Pounds, a.i. (millions)	375.1	382.6

986 Industry Profile Survey. National Agricultural Chemicals Association Schedule 2 and Schedule 3.

As can be seen by Table 3, the industry's own statistics show that the American farmer and rancher pays 50% less for their chemicals when there is open competition in the market.

In another effort to project the potential savings to farmers and ranchers, we have recently looked at four major herbicides used in U.S. agriculture. If the patent on each of these products had expired, generic competition had entered the market, and the price had dropped by 20%, the total annual savings on these four products alone would be approximately $208.6 million. These results are shown in Table 4.

TABLE 4

PRODUCT	Lasso	Dual	Bladex	Round-up
PE	1987	1993	1988	1991
PPP A.I. 1/	$4.92	$12.31	$4.68	$16.49
VOU (millions pounds a.i./year) 2/	85.0	38.1	4.9	8.0
TS PYW A 20% PRICE D (millions)	$83.8	$93.8	$4.6	$26.4
TAS	= $208,600,000			

1/ 1987 Retail prices Farmland Industries, Inc.
2/ Regulating Pesticides In Food, The Delaney Paradox, Board on Agriculture, National Research Council, National Academy Press, Washington, D.C. 1987

If only four major herbicides could result in a $208.6 million savings to farmers and ranchers, one must consider what the total savings could be for all products. We have estimated that if all pesticides were available, following patent expiration, on a generic basis that the annual savings could exceed $500,000,000. With these types of savings potentials, it is easy to realize the total impact S. 746 could have on American agriculture.

Mr. Chairman, the second part of S. 1516 we wish to address today deals with patent term restoration. We have no objection to the extension of the patents on pesticides to insure that companies have an adequate return on their investment in new research and development. However, to allow the extension of patents without making adequate provisions for correcting the inequities in data compensation would only hurt our farmers and ranchers. By extending the patent without allowing for normal competition following the expiration of that patent would benefit only the patent holder and not the general public by keeping pesticide prices at elevated levels.

Moreover, the provisions for allowing for research and development to begin on patented products two years prior to the expiration of the patent do not go far enough. Research and development should not be prohibited on patented products when the intent is only to develop the government mandated data necessary to gain market entry following normal patent expiration. The time needed to prepare the data required to register a product takes five to seven years. To allow a company only two years to develop this data in effect provides an additional extension of the patent for an additional three to five years. This does not serve the needs of the public and only benefits the holders of patents once again providing them with additional exclusive marketing ability.

Mr. Chairman, the farmers and ranchers of our country need all of the help they can get to be able to produce their agricultural products in a competitive way. If we keep the cost of pesticides elevated because of the artificial barriers placed upon market entry by our laws, which only benefit a few major companies, then we are only hurting the people we are both here to serve, the American farmer and rancher. We can provide the necessary protection to the environment but, we cannot provide lower cost generic pesticides if we are unable to enter the market because of unreasonable data compensation or extensive extensions of the patents. With the changes I have suggested in my preceding testimony we can put hundreds of millions of dollars directly into our farmers' pockets without costing the American taxpayer a single dime.

In closing, Mr. Chairman, I would like to emphasize that we and other generic producers do not want a "FREE RIDE." Rather we want to be able to compete in an open market after the expiration of a patent. We are willing, and have spent millions of dollars in developing the data required by the EPA to support the continued use of older agricultural chemicals and will continue to do so. We believe that research and development companies should receive an adequate return on their invested dollars, but not at the expense of our farmers and ranchers.

Thank you for this opportunity to present our views on this important legislation.

STATEMENT BY

HARVEY S. GOLD, EXECUTIVE VICE PRESIDENT

NATIONAL PEST CONTROL ASSOCIATION

TO THE COMMITTEE ON AGRICULTURE

U.S. SENATE

ON

S. 1516

(A BILL TO AMEND FIFRA)

AUGUST 12, 1987

Mr. Chairman, let me begin by thanking you and the Committee for the opportunity to present the viewpoints of the National Pest Control Association (NPCA) on FIFRA amendments proposed for 1987 in S. 1516. NPCA is a world-wide organization representing specialists in the field of structural pest control. Pesticides are an essential resource in our work to control pests. Pesticides are not, however, our only resource for we use mechanical means wherever effective. We primarily use unrestricted, highly diluted, pesticides in small quantities. We use these materials to control insect and vertebrate pests, such as rodents, that pose threats to human health and property. We are concerned about the environment and focus a lot of attention on following EPA label directions with the pesticides we use. Over 98% of this industry's pesticides are the same materials you purchase at the local hardware store without any special permit or training to follow the label directions.

Support Certification and Training Provisions

NPCA's position, however, is that all commercial (for hire) pest control operators should be trained to apply the materials to the property of others. This is already mandated by state law in many states, and NPCA is urging that this be required in all states as now presented in the new proposed FIFRA amendments in S. 1516 and also in H.R. 2463 being considered in the U.S. House Agriculture Committee this session. The provision on certification and training in S. 1516 fulfills a goal of NPCA for all commercial structural pest control operators. Our Association has educational resources to help assure that the licensed pest control operators are trained to apply pesticides according to EPA approved directions. Most pest control operators have access to these through NPCA and their state associations and through extension service educational programs.

NPCA supported and worked hard to gain approval of these specific FIFRA amendments for strengthened training requirements in both the Senate and House bills last year. We were disappointed that final passage of the amendments was not achieved in last year's congress.

We do endorse most of the provisions in S. 1516, especially that on certification and training. We do, however, have concerns with parts of S. 1516 and would like to share these with you and propose ways we think the bill may be improved.

Criteria For Public Interim Administrative Review
Title II, Section 212, part (8) (b)

Item (i): "Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

Item (ii): Such criteria shall be established on the basis of levels of risk and may include consideration of currently available data." (Underlining added for emphasis.)

Our concern with the language of item (ii) is that it bases special review assessments of whether a pesticide is appropriate to use for either structural or agricultural uses on risk only, neglecting any possible benefits that the pesticide may have for protecting human health or the environment on which FIFRA registration decisions are based. We recognize that almost everything, if not everything,is based on evaluating relative benefits and relative risks. We ask that the Committee recognize and reinforce this basic practicality and insert in this set of criteria for registering and special review of pesticides, after the word "risk" in the (ii) section the phrase "versus benefits." Not to provide this basic criterion for EPA to use in making its decisions could very well deprive the country of many valuable pesticide resources needed for the protection of our food supply, our business and living accommodations and the greenery which we enjoy in our environment.

Indemnities
Title XIII, Section 1301

The proposed amendment in S. 1516 changes the law by specifying that indemnity payments must be approved by a line item in advance by Congress. We would like to point out to the Committee that over 80% of our membership of 2600 firms are small businesses. Our members buy their supplies of EPA approved pesticides for the season and many could be easily bankrupted by one emergency suspension decision by EPA. These pesticides are purchased in good faith and with no knowledge that the use may suddenly be terminated. EPA has, for example, just prior to the time when pesticides are purchased, announced that the product would be labeled for restricted use. Then, after the products are purchased, EPA changed its position to possible suspension. Without any knowledge of this policy reversal, a pest control operator, compelled to use only EPA registered products, is then penalized for a policy change by EPA. A compensation requirement will encourage EPA to consider the economic impact of their regulatory decisions.

Many jobs and many small companies could be affected by an emergency suspension decision by EPA unless arrangements are provided for compensation for the investments that businessmen have made for legally approved pesticides. We would like to point out that if advance notice is available, most firms are less likely to buy a product that may be cancelled or suspended, and thus, indemnification is a means to make the Agency assume responsibility for the timing of its actions. If EPA provides adequate notice, indemnification should not present a problem.

Therefore, we ask that the current indemnification language be retained in FIFRA.

Legal Standing For Antipesticide Advocates in Pesticide Cancellation and Registration Decisions

Title II, Section 212, Part (F)(i)(I)

"A notice of initiation of the public interim administrative review (shall include) opportunity for public comment on such notice."

The same provisions occur in Title V under Sections 503 and 505.

EPA's decisions on whether a pesticide is registered for use by our members and the public should be based on objective scientific based data -- not on emotional or media-driven fear of chemicals.

We request the Committee to remove from S. 1516 standing for persons that do not have any direct financial responsibility or investment from the bill's sections on registration and reregistration administrative process. This we believe will keep the decisions focused on relevant and factual data. Any factual data available from general public sources can be included in the administrative review process when it is admitted through EPA or the parties of direct financial interest. Legal standing in the registration/cancellation process is not essential for people that are outside of the current FIFRA language for eligible participants in the process. They clearly are represented through the public agency, EPA.

Generic Pesticide Registration

S. 746 (and H.R. 2569 in the House) is a separate bill to amend specific provisions of FIFRA relating to pesticide registration data availability and data compensation provisions after patent term protection has expired. S. 746 provides for an abbreviated application for registration of generic pesticides similar to the generic drug registration and patent term extension approved by Congress in 1984.

We at NPCA respectfully urge the Committee to approve S. 746 as a FIFRA related amendment as a means for increasing competition within the pesticide industry and reducing significantly prices for pesticide users and consumers.

In conclusion

Mr. Chairman, we support the certification and training provisions of S. 1516, but we feel the bill can be improved with changes. We recognize the bill is based on a negotiated compromise of a very broad spectrum of pesticide industry representatives, including user groups such as NPCA, and also of environmental activist groups going back to the last Congressional session. However, the above concerns were neither adequately addressed nor negotiated in last year's bill, and consequently, we think failure to address them will jeopardize passage of S. 1516 this session.

If agreements cannot be reached, we suggest the Subcommittee consider a simple reauthorization of the existing FIFRA. This would be a significant contribution to responsible pesticide management because EPA has already begun to implement key provisions of S.1516, including the sections on certification and training, groundwater protection, faster reregistration of pesticides and identification of inerts that may pose hazards to be treated as active ingredients.

Thank you, Mr. Chairman. We at NPCA look forward to working with you and the members of the Committee on possible FIFRA amendment alternatives this session.

STATEMENT OF THE NATIONAL FOREST PRODUCTS ASSOCIATION

BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
ON S. 1516,

THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT REFORM
OF 1987

July 30, 1987

The National Forest Products Association (NFPA) welcomes the opportunity to comment on S. 1516, a bill to reauthorize and amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The National Forest Products Association is a national trade association which represents the interests and views of owners and managers of forest lands, manufacturers of forest products, and affiliated regional and product associations. NFPA members apply pesticides and contract to have pesticides applied in forests, nurseries, and seed orchards. NFPA members also use pesticides in their wood product manufacturing processes.

The use of pesticides is an important part of modern forest management. Where needed, the judicious use of pesticides can increase dramatically forest productivity. In some situations, one well-timed herbicide treatment in a decades-long growing cycle can make the difference between a site being a valuable commercial forest and one that becomes overgrown and has no commercial value. Additionally, application of wood preserving pesticides extends the life of forest products up to ten times that of untreated products.

The forest products industry is one which is directly and substantially affected by the availability of pesticides. Although this industry manages millions of acres of forest lands, the number of acres treated annually and the volume of pesticides used in forest management are quite small relative to the nation's major agricultural crops.

Because of the relatively small market for most forest pesticides, there is far less incentive for a producer to seek a registration for one of these uses than for one of the nation's major food or feed crops. In fact, with the current cost of research and development of a new pesticide estimated near $40 million, no new pesticides are likely to be developed specifically for forestry. The forest products industry must rely on the registrations for major crops being expanded to include forestry uses. Therefore, access to new pesticides for forestry will depend to some degree on the difficulty of the requirements confronting registrants who wish to add a new use to an existing label.

The forest products industry, therefore, is vitally interested that any changes in FIFRA: (1) allow continued access to important forest management and wood preserving pesticides; (2) maintain incentives for registrants to register and market new pesticides for forest industry use; and (3) maintain or improve the soundness of the EPA pesticide registration process in order to ensure the safety of the pesticides the industry uses.

While certainly the pesticide manufacturers will be affected by FIFRA amendments, the ultimate impact of changes in the law will be felt by the nation's farmers, foresters, and consumers. NFPA urges the Committee, as it further considers S. 1516, to consider the needs of those who rely on pesticides to make a living, to protect their valuable property and crops, and to produce the nation's bounty.

NFPA's comments on those issues of primary concern to us follow.

Cancellation Hearings

S. 1516 dramatically changes the pesticide cancellation hearing process and the process for "public interim administrative reviews" (Special Reviews). While NFPA supports the ultimate goal of wishing to speed up and streamline the Special Review and cancellation processes, we urge Congress not to sacrifice the rights of pesticide users in that pursuit. This industry has participated in several Special Reviews and cancellation hearings, and it is our observation that many delays in the processes have been due largely to EPA ignoring its deadlines, not any inherent deficiency in the processes themselves.

The unworkable and short deadlines proposed for the cancellation process deny pesticide registrants and users the ability to effectively challenge EPA's proposed restrictions. Under current law, pesticide registrants and users have a right to test the validity of EPA's proposed restrictions on a particular pesticide use in a cancellation hearing. This right is one of the major strengths of FIFRA. Cancellation hearing procedures allow those who have invested considerable time and money in registering a pesticide, and those who depend on the pesticide to protect their crops, to have an independent assessment of the scientific and legal basis for EPA's proposal. The cancellation hearing is the best method contained in any environmental law for assuring a proper, scientifically sound decision on the merits.

The remedy for the perceived delay in reaching an ultimate Agency decision is not to tamper with the cancellation hearing. Instead, NFPA supports streamlining the interim administrative review process by setting time limits for the Agency to respond to comments. At the close of that process, however, the registrant and the pesticide user must be afforded the opportunity for an impartial independent review of EPA's scientific and legal conclusions through a cancellation hearing.

NFPA does not object to some shortening of the cancellation hearing process, especially in light of the expansion of the Special Review. The short, arbitrary time limits in S. 1516, however, are unworkable because they eliminate the fairness provided a pesticide registrant or user to present its own case fully and, most importantly, to test the EPA's case.

NFPA agrees that a cancellation hearing following a Special Review should take full advantage of the data and analysis compiled in the Special Review. The benefit of a Special Review, however, does not eliminate the need of those with an economic interest in the use of a pesticide to protect those interests in an independent forum. NFPA would be pleased to participate in any type of discussion aimed at shortening the process without destroying it.

NFPA objects to the provision granting standing in a cancellation hearing to parties without an economic interest in the pesticide. The environmental community is not constrained from participating in the EPA Special Review, which is the primary forum for discussing the risks and benefits of a pesticide use.

The courts have found that only those with an economic interest should be able to demand a cancellation hearing. In the "Chlorobenzilate Case," a federal court stated that only those with an economic interest in a pesticide have a right to argue that a use being denied them should be restored. If after a lengthy technical process, EPA decides that a given pesticide can be used under specific use restrictions, it would be wrong to allow those without an economic interest in the pesticide to be able to further burden those who rely on the pesticide for their livelihood.

Certification and Training

NFPA has long been a strong advocate of improved certification and training efforts for pesticide applicators. NFPA has worked and will continue to work with the Agency in improving training materials, as improved training of applicators is the best way of reducing pesticide risk and misuse. NFPA supports the certification and training amendments in S. 1516.

Pesticides in Groundwater

While NFPA recognizes the importance of the groundwater resource and has been supportive of efforts to protect groundwater, there are a number of provisions of concern to the industry in S. 1419 -- the Ground Water Safety Act of 1987 -- the likely groundwater amendment to S. 1516. In addition, given the number of states actively developing and implementing groundwater programs, EPA's continuing activities on the issue (including its recent "Agricultural Chemicals in Ground Water Strategic Plan"), and the progress being made toward passage of a groundwater research bill, this industry is not convinced that S. 1419 sets the proper direction for federal legislation.

NFPA's primary concerns with S. 1419, or any comprehensive groundwater bill containing comparable provisions, follow.

First, the definitions used in S. 1419 essentially equate all groundwater with drinking water. We would support a differential approach to protecting the resource which would allow the greatest protection to current drinking water and that which realistically is potential drinking water.

Second, S. 1419 would cause regulatory action to be initiated when a pesticide in groundwater reaches a fraction of what is called its "Groundwater Residue Guidance Level" or "GRGL." This number is tied to the maximum contaminant level goals (MCLG) established under the Safe Drinking Water Act, a non-enforceable ideal goal. The MCLG is a number set at a level which will result in no known or anticipated adverse health effects, with an adequate margin of safety. The maximum contaminant level (MCL) is the enforceable, drinking water standard set as close as feasible to the MCLG, taking into consideration other factors, but still fully protective of human health. By using MCLGs instead of MCLs as standards, S. 1419 raises the possibility of protecting water which is not, and may never be, used for drinking water to a standard way beyond what is used to protect actual drinking water elsewhere. We would encourage the Committee to revisit these numbers. Tying the GRGLs to the MCLs instead of the MCLGs would provide proper health protections, yet allow adequate flexibility for activities near those sources to continue responsibly.

Third, NFPA supports strong state involvement and flexibility in the development and implementation of any federal groundwater efforts, but there is one aspect of the state program's section of S. 1419 that is particularly troublesome. Under this bill, if a state, for whatever reason, has failed to submit an approvable program within the set time period, no pesticide which has the potential to leach may be registered for use in that state. This provision would effectively disallow the use of certain pesticides without the need to show actual scientific risk. It could also prove enormously disruptive to not only individual farmers, ranchers, and foresters, but to an entire state's economy as well. NFPA would strongly urge the Committee to delete this provision from the bill.

While NFPA has several concerns with the approach taken on groundwater in the House FIFRA bill, in our opinion, the direction taken there provides a more realistic, flexible method of protecting the groundwater resource.

Pesticide Regulation by Local Jurisdictions

The single, most broadly-held desire of the pesticide user community in amending FIFRA for some time has been to explicitly preempt local jurisdictions from regulating the sale and use of pesticides. Recognizing the controversial nature of such an amendment and in a continuing spirit of compromise, the many organizations supporting explicit preemption language have not pressed for an amendment. However, please understand the depth of our objection to an amendment to explicitly allow such regulation. NFPA would strenuously oppose any FIFRA bill which granted local jurisdictions the authority to regulate pesticides.

Local jurisdictions simply are not equipped to conduct the in-depth analysis required to make a valid decision on pesticide use. When regulations are based on fear, hysteria, or other unscientific grounds, the benefits lost from not using the pesticide are costly and unwarranted, as people rely on pesticides to: increase the productivity of their crops; protect their home values by killing termites; remove dangerous brush and grasses from right-of-ways; and protect their trees from insects such as gypsy moths.

In FIFRA, Congress gave EPA the primary responsibility for regulating pesticides. In passing the 1972 amendments to FIFRA, Congress granted the states a limited role in regulating pesticides. The legislative history is clear in stating that pesticide regulatory authority was extended to the states, but not local jurisdictions. The Senate Agriculture Committee Report states that FIFRA "should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides." 3 U.S. Code Cong. & Ad. News, p. 4008 (1972).

Like many of the issues being debated as possible FIFRA amendments, the issue of preemption of local pesticide regulation is not a new one. The arguments have been made before. NFPA sincerely hopes the Committee will not entertain any amendment to specifically grant pesticide regulatory authority to local jurisdictions.

Private Right of Action

A number of groups testifying before the Committee have asked for an amendment to allow individuals a "private right of action." The forest products industry sees such an amendment as unnecessary and as likely to create a mechanism to harass or stop pesticide applications. Misuse of a pesticide -- use not in accordance with the label -- subjects the applicator to an enforcement action by the state lead agency. If the use of a pesticide causes damage to a neighbor's property, 800 year-old tort law allows the neighbor to sue the applicator. There has been no showing -- of which we are aware -- that either the states or the courts are ignoring the complaints of their citizens in this area. The forest products industry is anxious to see that the application of pesticides to its lands, by employees or contract applicators, is done in strict accordance with the label. When our negligence causes damage to another's property we do not try to avoid our responsibility. However, we do not wish to have FIFRA amended to allow expensive lawsuits when there has been no loss or damage.

Reregistration Fees

As previously stated, the forest products industry is most interested that FIFRA and any changes in FIFRA provide no unnecessary roadblocks to manufacturers in registering and marketing new pesticides for forestry use. The proposed reregistration fees, unfortunately, may keep certain safe -- but marginally profitable -- pesticides from ever being reregistered for forestry.

While this industry does support federal cost saving efforts generally and also recognizes the need for increased resources to accelerate EPA's pesticide reregistration program, NFPA does not believe the costs of "fixing" this program should come to rest entirely on the registrant. First, while arguably the registrant does receive a "benefit" by virtue of a chemical's registration, so does the general public in most cases. Second, these additional costs will be passed on to the pesticide user. In many cases, that user, unable to pass on that increased cost, will be faced with even more economic distress than many face presently.

NFPA would urge the Committee to reconsider this provision.

NFPA thanks the Committee for this opportunity to comment on S. 1516, and would be pleased to discuss these and other relevant issues at the Committee's convenience.

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National Farm Workers Health Group

Marion Moses M.D.

Testimony of Dr. Marion Moses

Prepared For
The Senate Committee on
Agriculture Nurtrition and Forestry

Hearings on FIFRA Amendments

July 30,1987

My name is Dr. Marion Moses and I am very pleased to have the opportunity to submit testimony before the Senate Committee on Agriculture Nutrition and Forestry regarding health and safety concerns of farmworkers and FIFRA.

I am a physician specializing in environmental and occupational medicine and licensed to practice in the state of California. I attended Temple University School of Medicine in Philadelphia, trained in Internal Medicine at the University of Colorado in Denver and in Occupational Medicine at Mount Sinai in New York City. I am board certified in Occupational Medicine, an Assistant Clinical Professor at the University of California San Francisco, a member of the National Advisory Committee of the Farm Pesticide Safety Center at the University of California Davis, former director and now a consultant for the National Farm Workers Health Group which is affiliated with the United Farm Workers of America, AFL-CIO. I have had many years experience working with farmworkers on health and safety issues, especially as they relate to pesticide exposure.

The realities of agricultural practices and the lack of farmworker protection standards coupled with the inherent weaknesses in FIFRA assure that significant gains in health and safety of farmworkers cannot occur with the law as currently written and enforced.

Farmworkers are exposed to toxic pesticides from many sources -- the crops they cultivate and harvest, the soil the crops are grown in, drift of toxic sprays that are being applied to adjoining fields or often to the very field in which they are working. Farmworkers live in homes surrounded by fields which are heavily and repeatedly sprayed. Pesticides may be in the irrigation water, in the ground water from which their drinking water is drawn. And since they are more likely to consume produce very soon after harvesting they may get even more pesticide residues in their food than the general public. And since agriculture is the only industry in which children comprise a significant part of the work force, occupational toxic exposures begin at a very young age.

Not all pesticides used are acutely toxic, (that is do not cause immediate and obvious harm). This, does not mean they are "safe". Such pesticides may be the most hazardous of all in terms of chronic effects such as cancer and birth defects. From a public health point of view, low level chronic exposures are much more worrisome since there are not likely to be any signs of a problem until it is too late.

What is the extent of cancer, birth defects and other chronic effects among farm workers and their families? The answer is we don't know. But there are warning signs the problem may be a serious one.

McFarland, California, a small agricultural community in the Southern San Joaquin Valley near Delano was found to have an excess of cancer cases in children. From 1982 to 1985 when one childhood cancer case would have been expected, 8 were found. McFarland is completely surrounded by vineyards as well as cotton fields, almond groves and other crops all of which are extensively sprayed. The main source of exposure to carcinogens in the community are agricultrual pesticides. In the neighboring town of Delano, childhood cancer cases are also being reported that may be in excess of expected rates. Table grapes is the major crop in Delano. In another small agricultural town called Fowler in Fresno County, an excess of childhood cancer has also been found.

The types of cancer seen in some of the children are the same ones that have been found to be increased in farmers, agricultural workers and others exposed to pesticides in their work -- non-Hodgkins' lymphoma, leukemia and testicular cancer. And a recent study has shown that children are at increased risk of acute leukemia if their parents use pesticides in the home or garden.

There is also the concern with effects on the reproductive system. A farmworker who was exposed to teratogenic (birth defect producing) pesticides while working in the grape fields during her first months of pregnancy delivered a child without any arms or legs. The child was recently awarded an out-of-court settlement in a suit filed against Chevron and Stauffer chemical companies.

Because many pesticides are embryotoxic, they may be causing early spontaneous abortion (miscarriage) and therefore birth defects would not be seen because the fetus died very early in the pregnancy. There are studies that suggest farmworker women may be at increased risk for spontaneous abortion.

In California, the only state that mandates physician reporting of occupationally related pesticide illness, 1,675 such cases were reported in 1985. Since pesticide illness is grossly underreported (it is estimated that only 1% of pesticide poisonings in farmworkers are reported) the actual extent of work-related illness is much greater. From my experience, there are two main reasons for the underreporting. A major one is the justifiable fear on the part of the worker of employer retaliation and job loss. Also workers do not report illness because they must maximize their earnings during the harvest season and lose income if they take time off work to go to a doctor. And since employers often refuse to send the workers to a doctor for pesticide related health problems, the worker may be out of pocket for the trip to the doctor in any case. A second major reason for the underreporting is the abysmal state of knowledge of physicians in rural communities regarding recongnition and mangement of pesticide-related health problems in farmworkers. They often fail to even consider this diagnosis, or to dismiss it when it is raised by the worker. And since the basis of reporting of pesticide illness to the state is the "Doctors First Report of Work Injury" as part of Workers' Compensation, it can be seen why the majority of worker illness never enters the system at all. It has been estimated that 300,000 cases of farmworker poisoning from pesticides occur annually in the United States.

California is also the only state that has any data on occupational illness and injury rates for agricultural workers. In 1984, farmworkers' illness and injury rate of 48 per 1,000 was the highest in the state compared to 36 per 1,000 for workers in general industry. While farmworkers represent only 3.9% of the states' workforce, they accounted for 9% of reported fatalities, 8% of Workers' Compensation reports and 5% of compensable illness and injuries.

The Occupational Safety and Health Act (OSHA) was passed in 1970, the same year the Environmental Protection Agency (EPA) came into existence. Neither event has proved propitious for farmworkers. When OSHA attempted to set minimally stringent reentry standards for field harvesters in 1974, farm interests immediately moved to block the action and were able to disenfranchise farmworkers from coverage by this protective legislation. Farmworkers were thus left to the tender mercies of EPA which waited 12 years to propose worker protection standards. Proposals currently under consideration will not even begin to provide basic protections afforded other industrial workers.

The only way to determine the true extent of the acute and chronic health effects of pesticides is to monitor the use of pesticides and the health of the workers. However, there is no mandatory reporting required by FIFRA for either pesticide use or pesticide illness. Such records provide the basis for epidemiological investigations required to assess health risks of pesticides.

FIFRA should require mandatory reporting of all pesticide use on agricultural crops. Mandatory reporting of pesticide illness, incidents, accidents and misuse and abuse should also be required.

All such records should be kept for 30 years. All such records should be in the public domain and be readily available upon reasonable request. Such records should be immediately available to the worker, his or her doctor or representative upon request in any exposure situation where human health risk is being assessed.

FIFRA should come into compliance with other legislation that forbids carcinogenic residues in the food supply. Carcinogenic pesticides should be banned and until they are stringent field reentry times and full posting should be required. All carcinogenic pesticides, proven or suspected irrespective of whether it is "weak" or not should be on the restriced list.

Any pesticide with missing acute or chronic toxicity data should have reentry times and full posting required, and be placed on the restriced list.

Any pesticide that was conditionally registered should have reentry times and full posting required, and be placed on the restricted list.

FIFRA should mandate that field workers be informed of the pesticides they are being exposed to. Only mixer/loader/applicators are currently required to be informed, and these regulations are observed more in their violation than enforcement. My experience has been that the workers who are "under the supervision of a certified applicator" are the least knowledgable and most at risk. The information provided to both non-certified mixer/loader/applicators and field workers should include the name of the pesticide, relevant acute and chronic toxicity data, (i.e whether it is a cholinesterase inhibitor, carcinogen, teratogen etc.), the risks to human health, the date the pesticide was sprayed and the legal reentry times for the specific crop they are working in, at a minimum.

FIFRA confidentiality provisions which prohibit EPA from disclosing information on inert ingredients should be repealed. Inerts can make up the major portion of the applied pesticide product and may be partly or mainly responsible for adverse effects. There should be no tolerance exemptions for inerts of toxicological concern.

Employers resist reporting since it involves what they consider to be burdensome paperwork. However they are subjecting their workers to a daily burden of toxic pesticides as part of their work environment. Workers have a right to know what pesticides they are being exposed to and how to protect themselves. This includes the "inert" ingredients.

Protection from toxic pesticides is an integral part of the farm workers grape boycott, where they are calling for the ban of 5 toxic chemicals used in grape production in California (Parathion, Phosdrin, Methyl Bromide, Captan, Dinoseb). I remind the committee that the first ban on DDT, Aldrin and Dieldrin in the United States was not by EPA in 1972 but in a farmworkers contract with a grapegrower in 1967.

Grapes is the largest fruit crop in California and receives more restricted use pesticide applications than any other fresh food crop (only cotton and sugarbeets are sprayed more.) Over half of all acute pesticide related illness reported in California involve the cultivation or harvesting of grapes.

Of the 79 million pounds of restricted use pesticides reported to be used in California in 1984, 6.4 million pounds of 75 different pesticides were used on grapes. Approximately one third of these are known or suspected carcinogens. Grapes were also found to pose 2% of the cancer risk attributed to pesticide residues in food in a recent National Academy of Sciences Report. A recent GAO report found that 34 of 76 (that is 44%) of the pesticides used on grapes which had potential human health hazards could not be detected by current multiresidue methods.

Amendments to FIFRA that would protect human health and the environment are powerfully resisted by the agricultural and agrichemical industries. It is estimated that it will take the EPA until well into the the 21st century to evaluate the safety of the pesticides currently being used on food. Is it not then understandable that the farmworkers have once again resorted to the boycott, in solidarity with labor, environmentalists, consumer activists, churches and concerned citizens, for the protections that the law does not provide.

STATEMENT
OF
ROBERT ABRAMS, ATTORNEY GENERAL
STATE OF NEW YORK
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
OF THE
UNITED STATES SENATE

AUGUST 17, 1987

I welcome the opportunity to comment on two Senate proposals, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Reform of 1987 (S. 1516) and the Ground Water Safety Act of 1987 (S. 1419). In New York State, outstanding agricultural productivity exists side by side with heightened awareness of environmental concerns. Both S. 1516 and S. 1419 attempt to meet the critical challenge of encouraging a thriving agricultural community while at the same time protecting our nation's environment, resources, and health.

I support many of the provisions of the FIFRA reauthorization bill, S. 1516. Together with S. 1419, the Ground Water Safety Act of 1987, it represents an important and long overdue awakening to a serious environmental problem. The potential harm posed by pesticides has been underestimated for far too long, to the detriment of our priceless water resources and our very health. The two bills now before the committee would go far toward correcting this dangerous trend.

I. FIFRA

Many provisions of S. 1516 fill gaps in the original FIFRA legislation. Several deserve specific mention. First, the public's need for access to information about the risks and benefits of specific pesticide products will be well served by two new provisions, Sections 102 and 213.

Section 102 would require label identification of the inert ingredients of pesticide products under certain conditions. Now the identity of all inert ingredients is considered proprietary information and must be disclosed only to EPA. Because inert ingredients typically compose over 80 percent of pesticides by volume, identification of these ingredients is essential to any meaningful assessment of the risk associated with exposure. Individuals, parents, doctors, employers and employees all need this information for obvious, if diverse, reasons.

Section 213 allows the public access to scientific data before a pesticide is registered. This will enable parties to comment on the propriety of registering a product on the basis of available scientific information before EPA permits a product to be registered, rather than after, as is now the case. The availability of penalties pursuant to 18 U.S.C. Section 1001 for false statements in affidavits filed in support of data requests made under Section 213 should adequately protect registrants from those who, under the guise of seeking information, intend to put the registrant at a competitive disadvantage.

The bill would ensure that the 600 active ingredients approved for use before November 1, 1984 meet current health and safety requirements as a condition of re-registration. I am particularly encouraged by the requirement under Section 217 for neurotoxicological and behavioral effects testing as a condition of both original registration and re-registration. In 1986, I joined a petition filed with the U.S. Environmental Protection Agency seeking to have EPA do precisely what S. 1516 demands of it: develop testing methods for these effects and then require registrants to submit such data in order to obtain or maintain product registration. The growing evidence from toxicologists, psychologists, pediatricians, allergists and even veterinarians and wildlife pathologists points ever more clearly to the potent effects which many pesticides have on the central nervous system and human behavior.

I strongly support several other provisions of S. 1516 which deserve specific mention: (1) Section 902 requires the registrant to disclose product data to states as well as to EPA, which is vital to provide state health authorities an adequate basis for making responsible public health decisions; (2) Section 1101 specifies that persons shall be liable under FIFRA for all acts of their officers and/or agents, plugging a vexing loophole in the existing statute and bringing FIFRA into agreement with principles of agency long embodied in the common law of many states; and (3) Section 1501 requires notice to foreign countries when pesticides being exported from the U.S. have been suspended or cancelled in this country, thereby ensuring that in solving our environmental problems at home we are not creating others elsewhere in the world.

Finally, Section 2003 laudably provides that EPA shall promulgate regulations to protect the health and safety of those who mix, load or apply pesticides and those agricultural employees who work in pesticide-treated areas. I firmly believe that federal regulation of worker health and safety should supplement, rather than supplant, state regulation. I would therefore urge adoption of additional language specifically stating that nothing contained in Section 2003 will preempt state statutes and regulations which set more stringent worker health and safety provisions than the federal regulations. This is particularly important since three of this nation's premier agricultural states, California, Texas and New York, have adopted worker health and safety schemes which provide a substantial measure of occupational protection for agricultural workers.

I also call upon the Committee and the bill's drafters to consider modifying Section 101(e)(4) and Section 401(d)(1)(B) of S. 1516 to require universal certification for all pesticide applicators. Our enforcement experience in New York has shown the need for certification of all those who commercially apply restricted-use pesticides. All too often, for example, an uncertified applicator may apply pesticides in violation of the label while the certified supervisor may be miles away, unaware of the applicator's actions. The uncertified person may not know the significance of the label warnings, but he or she actually applies the product. The certified person knows the requirements but has no personal contact with the product. Universal certification may not ensure universal compliance with label requirements. But the training entailed in the certification process does familiarize applicators with the properties of pesticides. Indeed, at least one major trade association of pesticide applicators here in New York now supports universal certification for commercial applicators.

I am very heartened to see that there is nothing in the FIFRA reauthorization bill suggesting an intent to preempt the states in regulating pesticide residue in and on food. The states should not be prevented from taking independent steps to protect their citizens, particularly in light of the federal government's thus far inadequate regulation in this area. Even with an invigorated EPA, we anticipate decades of further analysis before the completion of the pesticide re-registration process. Clearly, the task of protecting human health and the environment as we continue to derive economic benefits from prudent pesticide use is a sufficiently complex endeavor to warrant both federal and State attention.

Certainly, the states have an interest in uniform federal standards. Indeed, we in New York recently joined others in petitioning EPA to restrict the use of the pesticide daminozide nationwide. But the states should not be precluded by Congress from acting to protect the public health of its citizens when or if EPA fails to take steps to do so. Under the New York Constitution, our State government has a non-delegable duty to protect the public health. No Congressional action should impede us in carrying out this obligation through state initiatives when local conditions demand it.

For example, New York banned the termiticide chlordane several years ago, long before EPA entered into its recent agreement with the manufacturer to halt sales of all products containing this pesticide. New York's decision was based on a series of incidents of severe chlordane contamination in our state. In 1983 some homes on Long Island were actually rendered uninhabitable as a result of treatment with products containing chlordane and had to be destroyed as posing a significant threat to human health.

No single state could ever reasonably undertake a thorough review of each of the 50,000 pesticide products currently in use as EPA must ultimately do. It certainly could, however, respond to specific health threats posed by chemicals of particular concern in that state. I urge Congress not to limit the ability of New York or any other state to gather relevant data, conduct independent analyses of industry studies and set standards or restrictions necessary to protect our citizens.

In urging such federal-state cooperation, I am encouraged that S. 1516 provides for notice to state and local officials of the presence of canceled or suspended pesticides within their jurisdiction. Near Rochester, New York recently, two businesses -- the registrant and a pesticide distributor, both of whom would be covered by the new provision -- were warehousing, packing and shipping significant quantities of a banned pesticide with no notice whatsoever to the appropriate state or local authorities. Section 508 would close this loophole, and I strongly support it.

Just as strongly, however, I urge the Committee to consider deleting Section 1301 and the original provision, 7 U.S.C. § 136m, which require EPA to indemnify pesticide manufacturers whose products are ordered withdrawn from the marketplace. Section 1301 improves the present situation, in which manufacturers' indemnification payments come from EPA's programmatic budget, by requiring prior Congressional approval in the form of a line-item appropriation. In the final analysis, however, Section 1301 still places upon the American taxpayer the onerous and unjust burden of insuring chemical manufacturers against a normal marketplace risk -- i.e., new scientific evidence warranting regulatory change -- which many business entities face wholly without such protection. With due respect to this Committee, I do not believe that our citizens and taxpayers should be called upon to act as insurers of major manufacturers, whose research and development capabilities probably exceed that of most state governments.

II. Ground Water Safety Act of 1987

The groundwater protection measures proposed in S. 1419 are also a welcome step in the right direction. It is well known that almost half of all residents of the United States rely on groundwater as their primary source of drinking water.[1] Recent studies have described serious groundwater degradation in western and midwestern farming states such as Minnesota, Iowa and California. In Iowa, "recent investigations suggest that over 25 percent of the state's population is now exposed to pesticides through consumption of their drinking water."[2] In Minnesota, 38% of 504 water wells sampled recently tested positive for at least one pesticide.[3] New York is also among many states which have seen vital aquifers poisoned by the overuse or misuse of pesticides. The widespread use of aldicarb on potato fields on

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[1] "Contamination of Groundwater by Toxic Organic Chemicals," Council of Environmental Quality, p. xi (January 1986).

[2] "Pesticides In Iowa's Drinking Water," Richard D. Kelley, Iowa Department of Natural Resources, Des Moines, Iowa (October, 1986).

[3] "Minnesota Pesticide Monitoring Surveys Interim Report," Minnesota Departments of Health and Agriculture, St. Paul, Minnesota (October, 1986).

Long Island has been a major source of concern for the many thousands of residents who depend entirely on the Island's ground water. Between April and June of 1980, 1,025 drinking water wells were contaminated by aldicarb at levels above New York State health guidance standards.

Farther to the north in Eagle Bridge, a small town in New York's Rensselaer County, my office has brought an enforcement action against a custom applicator whose pesticide mixing, loading and disposal practices have contaminated groundwater. As a result of years of the applicator's careless practices, alachlor and atrazine have entered groundwater, and have been found in the nearest water well at levels approaching 1400 parts per billion - many times over state guidelines. These herbicides, sold as Lasso and Aatrex respectively, are widely used on the sweet corn which grows so well in the fertile bottom land along the Hoosick River.

Had the testing mechanism of the Ground Water Safety Act existed fifteen years ago, the initial well water tests which alerted the Rensselaer County Health Department to the existence of this serious problem would have triggered the provisions of Section 31(h)(5)(iv) permitting EPA to set "limitations on the method [of] pesticide handling or disposal." These limitations on herbicide handling or disposal might have reduced, or even eliminated, further contamination of this aquifer. Indeed, had EPA been able to amend the registration of alachlor and atrazine to require strict limitations on their handling and disposal when the problem first appeared, the water debacle at Eagle Bridge need not have occurred.

Congress, perhaps for lack of realistic alternatives, has always relied on labeling and upon the private sector's voluntary compliance with labeling as the cornerstone of federal pesticide regulation. Increasing evidence from our state enforcement cases makes us doubt the efficacy of labels in controlling some segments of the regulated community. We have encountered many problems caused by pesticide use or misuse which contravene the label requirements but are nonetheless in accordance with "widespread and commonly recognized practice." Most pesticide packaging states that violation of the label warnings constitutes a violation of federal law. But many users follow the informal recommendations of retailers, custom applicators, extension agents and other farmers. It is therefore important to acknowledge this reality of the marketplace, and I applaud the recognition of "common practice" as a factor triggering EPA action under Section 31(h)(1)(A) and elsewhere.

For example, let us assume that the labeling requires application of a pesticide at a rate not to exceed four pounds of the product per acre, but in fact local custom applicators typically used six pounds per acre. Let us further assume that no significant amounts of the product would leach to groundwater at the lower application rate, but that use at the higher rate would begin to impact upon groundwater. If EPA could only amend the product's registration if use in accordance with the label caused water contamination, the agency would be impotent to avoid further groundwater degradation. Section 31(h)(1)(A) will allow EPA to act as long as common practice is harming water quality. At this late date Congress should allow EPA to act without first having to prove a specific violation of label requirements. This provision will remove these official blinders.

Finally, I fully support the provisions of Section 31(o)(2) of S. 1419 and Section 1429(b) of the Safe Drinking Water Act which specifically permit the states to set and enforce stricter standards than those found in the federal groundwater residue guidance levels and regulations. This provision properly recognizes that in our federal system, the states remain the trustees of most natural resources and, as such, must be able to protect them as aggressively as their citizens and sound public policy demand.

Most of the requirements of S. 1419 will fall either on EPA or the registrant. But state agencies will have to provide significant coordination, oversight, data interpretation and management and outreach to affected pesticide users. Current resources in the responsible New York State agency will be inadequate to discharge these additional duties. The Committee, therefore, should devise a funding mechanism to enhance states' ability to assist EPA in implementing S. 1419.

The approach embodied in S. 1419 is a good one. We cannot wait for more aquifers to be polluted before sounding the alarm. The strength of this bill lies in its emphasis on anticipating pollution before it reaches levels of concern. If implemented properly, the Ground Water Safety Act of 1987 will go far to prevent further destruction and degradation of our precious water resources.

I applaud the efforts of the sponsors of these two far-sighted proposals and strongly urge their passage without weakening amendments.

STATEMENT OF THE PESTICIDE PUBLIC POLICY FOUNDATION

BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

ON S. 1516
THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
REFORM OF 1987

July 30, 1987

The Pesticide Public Policy Foundation (3PF) is pleased to submit this statement in conjunction with the Committee's consideration of S. 1516, a bill to reauthorize and amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). S. 1516 is based on last year's House compromise bill. The oral statements on S. 1516, however, showed little interest in compromise. As FIFRA legislation moves to markup, we ask that the Committee take a close look at the needs of those who use pesticides. Please do not look at the FIFRA amendment process as a conflict between environmental groups and the agri-chemical business. The comments which follow express the view of an industry which is directly and substantially effected by FIFRA and its regulations. The ultimate impact of changes in the law is felt by people who use, depend on, and apply these pesticides. We urge the Subcommittee to consider the needs of these groups in reviewing any proposals to change FIFRA.

3PF is a national, non-profit corporation representing urban, suburban and green industry users of pesticides. Specifically, 3PF membership includes tree service, lawn care, pest control operator, golf course, landscape maintenance, and other pesticide user interests. Because our members, their families, and employees are occupationally exposed to pesticides we are vitally interested in pesticide safety and the adequacy of pesticide training and certification. In addition, because many of our members are engaged in selling a service to the public, we are interested in the public's perception of how well the Agency protects the public through the registration process. Finally, as businessmen and women, our members are concerned that unnecessary and unworkable regulations (especially at the local level) will place new and substantial burdens on our industry. Burdens caused by unnecessary regulation do not add any increment of safety, but merely punish those who must comply.

3PF is submitting this statement and will continue to actively participate in the FIFRA amendment process to represent the interests of the green industry in an effort to arrive at a bill which promotes the interests discussed above. Some provisions in S. 1516 are helpful, but others present problems for pesticide users. Some of the specific issues rasted at the July 30, 1987 will be raised at markup also are of substantial interest to 3PF memebers. Our comments on specific provisions follow.

Certification and Training

3PF and its members have been strong advocates of improved pesticide training, certification, and recertification as the best way to promote pesticide safety and adherence to the label. Application technology has progressed to a stage that off-target deposition and quantity of pesticide used can be dramatically reduced. These benefits, however, are only available to those who receive the training. FIFRA does not require training for commercial applicators unless they use restricted use pesticides. Restricted use pesticides, however, account for a very small minority of the pesticides used by urban and suburban commercial applicators. We believe that the existing FIFRA does not adequately speak to the need for verifiable training for all commercial applicators.

We strongly support the certification and training provisions in the bill. In particular, we support the concept of a legislatively recognized category of registered commercial applicator. Similarly, we support mandatory recertification. 3PF also supports the emphasis placed on improving the training materials. We, and our members, have worked with EPA, the Extension Service, and the states in efforts to help improve the quality and currency of pesticide training materials. We look forward to continued work with these agencies to update and improve their materials.

S. 1516 also recognizes two other groups in desperate need of training -- the trainers themselves and enforcement officers. Just as there is much to learn about pesticide application there is much to learn about how to train others. A good trainer should know his/her material as well as how to convey that information to the prospective pesticide applicator. Similarly, if an enforcement agent is not conversant with how to properly apply the pesticide, how good a job can he/she do in judging the work of others. In short, 3PF supports the certification and training provisions in Title IV of S. 1516.

Cancellation Hearings

The bill dramatically changes the pesticide cancellation hearing process and the process for "public interim reviews," Special Reviews. We share the ultimate goal of the Environmental Protection Agency, the historical sponsor of this amendment, in wishing to speed up and streamline the Special Review and cancellation processes. In an apparent attempt to speed up the process this amendment substantially reduces the ability of a pesticide registrant or user to defend the use of a pesticide indicted by EPA. The delay in the process has largely been due to EPA ignoring their deadlines, not any inherent deficiency in the process.

Under current law pesticide registrants and users have a right to test the validity of EPA's proposed restrictions on a particular pesticide use in a cancellation hearing. This right is one of the major strengths of FIFRA. Cancellation hearing procedures allow those who have invested time and money in registering a pesticide, and those who depend on the pesticide to protect their crops, to have an independent assessment of the scientific and legal basis for EPA's proposal. The cancellation hearing is the best method contained in any environmental law for assuring a proper, scientifically sound decision on the merits.

The remedy for the perceived delay in reaching an ultimate agency decision is not to tamper with the cancellation hearing; instead, 3PF supports streamlining the interim administrative review process by setting time limits for the Agency to respond to comments. At the close of that process, however, the registrant and the pesticide user must be afforded the opportunity for an impartial independent review of EPA's scientific and legal conclusions through a cancellation hearing.

We do not object to some shortening of the cancellation hearing process, especially in light of the expansion of the Special Review. The short, arbitrary time limits in the bill are unworkable. They do not allow parties challenging an Agency action sufficient time to protect their rights under the law. In that way the proposal eliminates the fairness provided a pesticide registrant or user to test the EPA staff's case. 3PF agrees that a cancellation hearing following a Special Review should take full advantage of the data and analysis compiled in the Special Review. The benefit of a Special Review, however, does not eliminate the need of those with an economic interest in the use of a pesticide to protect those interests in an independent forum. 3PF would be pleased to participate in any type of discussion aimed at shortening the process without destroying it.

3PF opposes the provision which would overturn the "Chlorobenzilate Decision" and grant those without an economic interest in a pesticide use the ability to demand a cancellation hearing. Such an amendment is unnecessary and provides a substantial opportunity for harassment of pesticide registrants and users. Nothing in FIFRA as currently written, or as it would be amended by S. 1516, would deny anyone a chance to fully participate in a Special Review. After the Agency has made its decision in the Special Review (with full input from the environmental community) only those harmed by that decision should have the ability to challenge it. If a registrant or user demands a cancellation hearing to challenge the decision, those environmental groups are permitted to participate.

In the "Chlorobenzilate Case" the federal court stated that only those with an economic interest in a pesticide have a right to argue that a use being denied them should be restored. If after a long process, EPA decides that a given pesticide can be used under specific use restrictions, it would be wrong to allow those without an economic interest in the pesticide to be able to further burden those who rely on the pesticide for their livelihood.

A cancellation is a very costly undertaking. This is because proving benefits is an expensive, highly quantitative undertaking. In addition, it is always difficult and expensive to prove a negative -- in this case, lack of unreasonable risk. Registrants and users resort to the cancellation hearing only when: (1) they feel strongly about the strength of their case; and (2) the market about to be lost is sufficiently large to warrant the expense. If those without an economic interest are granted the ability to demand a hearing, they would not be faced with the factors which currently limit the number of cancellation hearings. Frankly, allegations are easy and inexpensive to make. The harassment aspect is raised because a group or individual can inexpensively demand a cancellation hearing after an extensive Special Review and thereby require the pesticide registrants and users to mount a costly defense.

Regulation of Pesticides by Local Jurisdictions

3PF would opposed any FIFRA bill which granted local jurisdictions the authority to regulate pesticides. The single, most broadly-held desire of the pesticide user community in recent years has been amending FIFRA to explicitly preempt local jurisdictions from regulating the sale and use of pesticides.

Local jurisdictions simply are not equipped to conduct the sophisticated scientific analysis required to make valid decisions on pesticide use. Regulations based on fear, hysteria, anectdotal evidence, or other unscientific grounds unnecessarily and inappropriately deny pesticide users the benefits of those uses. Such regulations are unwarranted, and as consumers, harm us all.

People rely on pesticides to: protect their home values by controlling termites, keep their lawns green, remove dangerous brush and grasses from right-of-ways, protect their trees from insects such as gypsy moths, and increase the production of their crops. There is also a group of people whose livelihoods depend on access to effective pesticides -- the commercial applicator. In FIFRA, Congress gave EPA the primary responsibility to regulate pesticides. In passing the 1972 amendments to FIFRA Congress granted the states a limited role in regulating pesticides. The legislative history is clear, however, with regard to the authority granted to political subdivisions below the state level. The Senate Agriculture Committee Report states that FIFRA "should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides."

Two courts have handed down decisions on the issue of pesticide regulation by local jurisdictions this summer. The Supreme Court of Illinois held that two state pesticide laws so comprehensively regulated the use of pesticides that the village of Wauconda was preempted from enacting its ordinance regulating the use of pesticides. Pesticide Public Policy Foundation v. The Village of Wauconda, Docket No. 63297.

The same day, the U.S. Court of Appeals for the Fourth Circuit handed down its decision in Maryland Pest Control Association v. Prince George's and Montgomery Counties, MD, No. 86-3633. In that decision, the Court upheld the decision of the lower court that "the legislative history [of FIFRA] indicated that Congress intended to restrict authority to regulate to states and not extend it to their political subdivisions." 3PF and its members participated in both of these cases and are certainly pleased with the outcomes. These lawsuits were effective in lifting unwarranted and illegal burdens off our members. We are hopeful that these decisive decisions will deter other local jurisdictions from illegally imposing restrictions, but there is no guarantee that we will not need to fight this issue again and again in more of the nation's estimated 80,000 local jurisdictions. One way to help guarantee that local jurisdictions will stop their regulations is to make the federal preemption more clear with a FIFRA amendment.

As stated above, however, 3PF is not using this statement as an exposition of its FIFRA "wish list." Rather, we are trying proceed in the prevailing mood of compromise. As such, we have chosen not to fight for our greatest wish out of FIFRA -- explicit preemption of pesticide regulation by local jurisdictions. That compromise position will, of course, need to be changed if the Committee entertains an amendment to specifically grant pesticide regulatory authority to local jurisdictions.

Reregistration Fees

3PF remains concerned that reregistration fees may provide a disincentive for registrants to make pesticides available for our use. The application of pesticides by 3PF members are minor uses. We are not a major crop. Even taken as a whole, our members do not provide a sufficient potential market to justify a registrant´s special attention. We rely on the use of pesticides created and registered for other uses. We fear that the reregistration fees, may stop registrants from granting us access to existing and future pesticides.

Patent Term Restoration

3PF recognizes that the future of our urban and suburban pesticide uses depends in large part on gaining access to new pesticides. We also note that only a handful of companies remain in the business of doing the necessary research to develop new pesticides. It is essential to our future well-being that these companies have the incentive to do the necessary research and register new pesticides. Based on our own long-term self interest, we support patent term restoration for pesticide registrants.

Conclusion

In addition to the specific comments above, we wish to leave the Committee with the message that the Pesticide Public Policy Foundation is most interested in being part of the FIFRA amendment process. 3PF would be pleased to discuss or expand on these comments at the Committee´s convenience.

NATIONAL
COUNCIL OF
AGRICULTURAL
EMPLOYERS

July 28, 1987

The Honorable Patrick Leahy
Chairman
Committee on Agriculture, Nutrition and Forestry
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your gracious invitation to present testimony at your hearing on S.1516, a bill to reauthorize the Federal Insecticide, Fungicide and Rodenticide Act, on July 30, 1987.

While I would very much like the opportunity to present testimony in person; or arrange for an officer or Board member to present NCAE's position on this very important matter, unfortunately this is impossible due to unavoidable schedule conflicts. This in no way reflects upon NCAE's desire to work with you, and your staff, toward a bill which substantially addresses our mutual concerns.

Toward that end, I enclose a copy of the statement which we would have otherwise delivered in person Thursday.

NCAE would like to congratulate you upon your willingness to tackle this important and complicated issue and we stand ready to work with you as the Committee moves forward with S. 1516.

Sincerely,

Libby Whitley

Elizabeth D. Whitley
Executive Vice President

cc: The Honorable Richard Lugar

Enclosure

499 South Capitol Street, S.W. • Suite 411 • Washington, D.C. 20003 • (202) 488-1100

STATEMENT BEFORE THE
COMMITTEE ON AGRICULTURE. NUTRITION AND FORESTRY
U.S. SENATE

July 30. 1987

NATIONAL COUNCIL OF AGRICULTURAL EMPLOYERS

The National Council of Agricultural Employers is pleased to be able to share its views on certain provisions of S. 1516. a bill to amend and reauthorize the Federal Insecticide. Fungicide and Rodenticide Act (FIFRA). and it also would like to commend the Committee for its efforts on this complex issue.

The National Council of Agricultural Employers. known as NCAE. represents over four hundred members in thirty-five states. The diverse membership is made up of individual growers, grower associations and cooperatives, state horticultural and commodity associations, national trade associations and other groups. NCAE members raise primarily fruits. vegetables. livestock and specialty crops.

NCAE was established in 1964 to represent grower interests specifically on agricultural labor issues. In fact. NCAE is the only major national association focusing exclusively on agricultural labor matters and it represents employers hiring about 75% of the agricultural work force.

Most members are represented through other trade associations on issues such as credit. commodity. trade and pesticides. Because of this. NCAE associates itself with other grower groups' positions on the wide range of issues treated in S. 1516. the FIFRA amendments of 1986. These groups include the United Fresh Fruit and Vegetable Association. the Society of American Florists. the National Food Processors Association. the American Association of Nurserymen. and others.

However, NCAE sees significant potential for major farm labor-related precedents included in S. 1516. Because of NCAE's role as a major voice for the agricultural industry on farm labor issues, it would like to highlight three major problems associated with S. 1516 as introduced.

Worker Health and Safety, Sec. 2003

Our first and most obvious concern with S. 1516 as introduced is Sec. 2003, the worker health and safety provision.

NCAE, together with the United Fresh Fruit and Vegetable Association, the Nurserymen and the Florists, expressed its strongest objection to the inclusion of similar language in last year's bills without the benefit of hearings before either House or Senate Committees.

Developing regulations which protect farmworkers without placing undue economic and operational burdens upon growers is a tremendously complicated process. NCAE has always been a strong supporter of adequate protection for farmworkers from the health hazards of pesticides. At the same time, it believes Congress must scrutinize closely the proper vehicle to achieve such protections for farmworkers: whether by law in FIFRA or by administrative fiat at EPA.

After consideration, NCAE urges deletion of Sec. 2003 from S. 1516 for two reasons.

First, EPA will propose a new, substantial expansion of the present 40 CFR Part 170 farmworker pesticide protection regulations sometime this summer. This would render Sec. 2003 moot. A brief discussion of the background of the EPA rulemaking is helpful in illustrating this case.

When this Committee considered FIFRA in 1986, farmworker representatives had just "walked out" of the EPA 1985-86 worker protection Regulatory Negotiation Project (RNP) and it was unclear whether the agency would continue with the proposed revision of the existing Part 170 regulations. For this reason, some thought Congress needed to direct EPA to act on worker pesticide protection regulations.

Regardless of the actions of farmworker groups, EPA plans to complete its revision of Part 170 regulations governing farmworker pesticide protection. Therefore, NCAE believes Sec. 2003, with its directive to the agency to develop regulations, is superfluous. The matter is being dealt with by the Agency with no need for statutory direction.

NCAE has extensive experience with development of farmworker pesticide protection measures. In the early 1970's NCAE participated in agency, industry and union discussions which resulted in the current Part 170 regulations.

NCAE was one of nine agricultural industry negotiating team members during the 1985-86 EPA RNP, and it observes that both EPA and industry perception of the worker protection issue has matured over the past three years.

Grower representatives agreed, after reflection upon the negotiated rulemaking, that revision of existing Part 170 regulations was justified and timely. However, growers also maintained that EPA, while obviously committed to stepped-up farmworker protection requirements, lacked the data on pesticide use, crops and application practices necessary to pinpoint the major pesticide exposure problems.

For example, EPA could not estimate how many cases of "pesticide exposures" occurred annually...and could not define what was a "hazardous exposure to pesticides." The industry felt that, in order to craft any practical, economically justifiable and enforceable regulation, the scope of the pesticide exposure problem first had to be identified; in this case, the national rates and types of pesticide exposure-related illnesses and fatalities.

Industry didn't claim "that you shouldn't fix what isn't broken". Rather, it was felt that if you can't tell how something is broken it will be difficult, in all likelihood, to figure out any way to fix it and, sometimes, when you're done, whether you've fixed it at all.

NCAE comments to EPA urged the agency to move carefully, pending more research on the extent of the exposure problem, and indicated that the surest protection would come through the reregistration process on a pesticide-by-pesticide, crop-by-crop basis.

Recognizing, however, the timely need for reasonable revisions to the current Part 170 standards NCAE proposed a number of interim steps EPA could take pending such reregistrations.

NCAE endorsed a 24-hour reentry interval for Toxicity I chemicals except for those already possessing longer reentry intervals. It recommended that warnings and hygiene instructions be posted at a central location, and include other information such as the address and telephone number of local emergency facilities. It agreed that pesticide handlers who had the greatest exposure should wear appropriate protective clothing, and that training should be given to any individual mixing, loading or applying pesticides.

Industry's concerns were two-fold. First was that regulations be usable for both grower and farmworker. Second, NCAE was deeply concerned about the liability potential. Frankly, Mr. Chairman, the grower liability potential is the second, and perhaps more important reason, that even general statutory directives such as are embodied by Sec. 2003 in S. 1516 are problematic and ill-advised at this time.

NCAE is concerned that creating a statutory federal farmworker pesticide protection program opens the door to grower liability as a result of deliberate worker non-compliance, particularly should a private right of action be included in FIFRA or later inferred.

Private Right of Action

NCAE opposes in the strongest possible terms any inclusion of language establishing an individual's right to bring suit in federal court, exclusive of any administrative actions or remedies. It won't comment upon such a private right of action's effect on general uses of pesticides in the United States, as that would be speculative and outside the scope of both NCAE's expertise and the purpose of these comments.

An explicit or inferred private right of action, when applied to the worker health and safety program as envisioned by Sec. 2003, would have the effect of permitting workers or their representatives to bring suit in federal court and potentially enforcing massive monetary fines against grower employers for even minor or technical violations of FIFRA. Section 1201 of S. 1516 allows for fines of up to $2000 per violation. While this does not, admittedly, authorize damages *per se*; courts could use this figure as a means for awarding appropriate punitive damages for violations of the worker health and safety regulations.

The effects of a private right of action are already clearly illustrated in the brief history of the Migrant and Seasonal Agricultural Worker Protection Act (MSPA). MSPA governs housing standards, motor vehicle safety, wage and hour recordkeeping, notification of working conditions and other important worker protections. MSPA's private right of action enables workers to bring suit against employers exclusive of administrative remedy and permits workers to recover up to $500 per violation against an employer--for any violation of the law, even de minimus and technical violations where no actual injury is alleged or proved.

This law, since its enactment in 1983, has cost growers millions of dollars in attorneys' fees, settlement costs and--rarely--in jury awards in cases brought by farmworker legal advocates. Alleged violations usually involve violations such as failure to post working conditions, torn screens on housing and similar instances where little actual worker injury has occurred. One grower in Florida, for example, was sued for failure to note on pay stubs how much each worker earned under a piece rate method of pay versus how much was earned on an hourly rate. Only in rare instances do plaintiff attorneys try to negotiate with grower to correct the alleged violations. Most frequently growers first hear of alleged violations when served with the complaint filed in federal district court.

MSPA contains only thirty specific standards with which employers must comply. Under the EPA worker safety regulations there are at least thirty specific requirements in the protective clothing section alone. The potential for abuse of the provision and for harassment of growers, using the double club of a statutorily-mandated worker health and safety program and a private right of action provision in FIFRA, is deserving of the most careful consideration and, NCAE believes, rejection.

Duplicate and Overlapping Jurisdictions Between EPA and OSHA; Sec. 1701

Sec. 1701, the delegation and cooperation section, negates Sec. 4(b)1 of the Occupational Safety and Health Act (OSH Act) and, if it remains in S. 1516, OSHA would be permitted although not required to establish worker safety and health regulations parallel to EPA's.

EPA's present Part 170 worker protection regulations were promulgated as a result of court cases in the last 1960's and early 1970's which established EPA's primacy in all pesticide use and application safety and training issues.

NCAE believes strongly that this language, if permitted to remain in the bill, would result in duplicative, costly, overlapping and confusing regulation of pesticide use. It makes meaningless the directive to EPA to develop worker safety and health provisions and provides a second forum for advocates of strong, prescriptive worker safety and health regulations to lobby their case.

As such, we believe that Section 1701 should be eliminated from the bill.

Conclusion

NCAE commends the Chairman and Committee for considering the matter of reauthorization of FIFRA. There are many important and valuable reasons to do so. However, NCAE believes that S. 1516 establishes undesirable new precedents in the areas of worker health and safety and the overlapping EPA-OSHA juridictional issues. For these reasons we urge you to eliminate both Section 2003 and Section 1701 from S. 1516. Further, we oppose in the strongest possible terms the inclusion of an explicit or inferred private right of action in any reauthorization of FIFRA and urge the Committee to resist any attempts to add such language.

Beyond these fairly narrowly-described issues, NCAE shares many of the concerns outlined by other grower groups represented before the Committee.

Thank you again for this opportunity. NCAE stands ready to assist the Committee in any way it can.

STATEMENT OF THE NATIONAL COTTON COUNCIL OF AMERICA ON THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

July 30, 1987

SUBMITTED TO
SENATE COMMITTEE ON AGRICULTURE

The National Cotton Council headquartered in Memphis, Tennessee, represents producers, ginners, seed crushers, warehousemen, merchants, cooperatives, and textile manufacturers from the Carolinas to California.

The cotton industry strongly supports a clean environment and safe use of chemicals. However, we are gravely concerned about the continued availability of essential pesticides that are currently registered and about the development and registration of new pesticides that are safer, more effective and less expensive.

We recognize the need for, and support, reasonable regulations for pesticides. However, we are concerned about imposition of unnecessary rules that would make many essential pesticides unavailable to farmers even though they are registered and in the marketplace.

At the Council's 1987 Annual Meeting, delegates representing all seven segments of the U.S. cotton industry unanimously adopted the following resolution on pesticides:

Continue supporting legislation and other measures to facilitate sound development and use of essential agricultural chemicals, and, in particular:

- Urge expeditious clearance of needed new cotton pesticides; continued registration of older pesticides unless there is scientific proof that their use presents an imminent hazard or that the risks outweigh the benefits; and seek ways to assure continued availability of non-proprietary pesticides under the data call-in and reregistration process;

- Urge that buffer zones, minimum dilutions, and other pesticide application restrictions be imposed only upon valid, scientific proof that they are necessary to prevent a physical health hazard to humans or animals;

- Continue to support federal and state preemption for overall pesticide regulatory authority and federal preemption for setting residue tolerances; and support continued use of residue action levels where appropriate in absence of tolerances; and

- Continue to encourage appropriate use of cottonseed oil as a pesticide carrier and in pesticide formulations; assess research needs and encourage

> studies so that maximum benefits of this technology can be realized; support federal and state regulatory actions and data requirements that do not restrict registrations and use of pesticides with cottonseed oil unless there is scientific proof that there are increased hazards which outweigh increased benefits; and urge regulatory agencies, in determining the need for such requirements and restrictions, to consider the safety record of previous use on an individual crop basis.

We have some very strong concerns that need to be addressed by amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Before taking our positions on these, we recognized and took into consideration three fundamentals.

First, changes made in the law should not deny or unjustifiably restrict the use of pesticides by farmers and/or increase their production costs.

Members of this Committee are very familiar with the economic situation on U.S. farms. You read and hear about the large number of farms "going under". We believe that you don't want to pass legislation that would add to the already heavy economic burden for U.S. farmers.

Second, amendments to FIFRA should not increase the resource burden to the U.S. Environmental Protection Agency (EPA) or the state agencies responsible for administering the law.

We support the overall thrust to move toward a balanced budget. One of the easiest and most "palatable" approaches is to eliminate, and certainly not add any new, unnecessary regulatory legislation, the costs of which outweigh the potential benefits.

Third, the environment should be protected to no less degree than the current FIFRA provisions provide.

As stated earlier, we strongly support a clean environment and safe use of agricultural chemicals.

Specific concerns of the Council are discussed in greater detail in the sections that follow.

Federal and State Preemption for Overall FIFRA Authority -- When the major overhaul of FIFRA was made with the 1972 amendments, Congress granted limited authority for states to regulate pesticides. Legislative history indicates the Congress intended to share Federal authority with the States, but not with local jurisdictions. Yet, there have been numerous incidents where city and county governments have embarked on efforts to regulate pesticides at the local level.

Both the National Association of State Departments of Agriculture and the Association of American Pesticide Control Officials have endorsed Federal and State preemption to regulate pesticides.

Having different local regulations is unnecessary and will create unworkable situations and undue hardships for farmers and other users. The National Cotton Council strongly endorses amendments making it clear that FIFRA does not extend pesticide regulatory authority to local jurisdictions beyond the state level.

Federal Preemption for Setting Pesticide Tolerances -- Agricultural commodities and products made from agricultural commodities must be allowed to move across state lines without any unnecessary restrictions. It is completely unworkable and unnecessary for states to set pesticide residue tolerances. In addition to being costly, it would create mass confusion where the same commodity had different tolerances for the same pesticide in different states. States don't need and should not have the authority to adopt the same tolerances set by EPA because that could result in increased program costs for the states.

We strongly support amending FIFRA to provide for Federal preemption in this area.

Tolerances For Imported Agricultural Commodities -- The Cotton Council strongly favors FIFRA language requiring all imported agricultural commodities and their processed products to meet U.S.

tolerance standards for pesticide residues. Allowing pesticide residues in excess of U.S. standards is totally unfair to U.S. growers who must bear the cost of meeting the standards.

Fees For Registering and Reregistering Pesticides -- In the past few years, there has been a movement underway to shift costs from the government and taxpayers-at-large to specific groups that are the principal users of the services or materials. As the movement continues, anyone who requests information will be required to pay the cost of collecting and distributing information.

EPA has been charging rather large fees for setting pesticide residue tolerances. Recently these fees were increased substantially. In a sense, the tolerance fees are "registration" fees since most pesticides must have tolerances established in order to be registered.

There are two Federal statutes that require pre-clearance of specific products before they can be manufactured, sold and used. One is FIFRA and the other is the Federal Food, Drug, and Cosmetic Act (FFDCA). In each case, pre-clearance and registration of products broadly benefit the general public.

Congress has consistently rejected registration fees for drugs. This should set a precedent for rejecting registration and reregistration fees for pesticides. Pesticides should not be singled out for special user or registration fees when other products such as drugs under pre-clearance statutes are specifically exempted from such fees.

Such fees would:

- Result in higher pesticide costs that would be passed on to farmers and ranchers who, historically, have not been able to pass on such costs to consumers of farm and ranch commodities;

- Tend to restrict innovative research and development especially of (1) products for use on minor crops and minor uses on major crops and (2) products that may be safer and more environmentally sound yet not any more biologically effective in controlling target pests.

  For minor uses (uses with low market potential), imposition of registration fees could actually be a major factor in a company's decision not to pursue registration;

- Have a disproportionate and unfair adverse impact on small businesses.

- If used to pay most of EPA's expenses, the fees would remove most cost constraints on the Agency regulatory operations. Also, it would leave little incentive for Congress to scrutinize EPA's programs to see if they are necessary and/or cost-effective; and

- It will be virtually impossible, particularly with flat fees, to distribute the costs equitably among registrants and users.

Use of Restricted-Use Pesticides Under Direct Supervision of a Certified Applicator -- With the 1972 FIFRA amendments, Congress wisely provided that restricted-use pesticides may be applied by a certified applicator or by a person under the direct supervision of a certified applicator. Over the last 2-3 years, EPA and several environmental, labor and consumer groups have suggested amending FIFRA to eliminate the provision that allows restricted-use pesticides to be used "under the direct supervision" of a certified applicator. The justification given is that under the present statutory language, the Agency's ability to limit use to competent applicators can (emphasis added) be easily thwarted. The truth is no one has presented any factual evidence to show that there have been problems during the past 13 years under the present statutory language.

We contend that removing the phrase "under the direct supervision of a certified applicator" will create hardships on farmers whether or not it is the farmer himself or someone else such as a private agricultural consultant hired by the farmer who is the certified applicator that supervises the use. Therefore, the

National Cotton Council endorses the present FIFRA language on this subject.

Lack of Essentiality Should Not Be A Criteria Against Registration of Pesticides -- In 1972, Congress, in its wisdom, provided under Section 3 of FIFRA that "EPA shall not make any lack of essentiality a criterion for denying registration of any pesticide" (emphasis added). That is, just because a pesticide is already registered for the same use, another pesticide should not be be denied registration for that use.

Congressional intent is being thwarted by EPA contending that the "lack of essentiality" provision in the law does not apply to conditional registrations. Practically all new products are being given conditional rather than full registration.

We believe that Congress' intent was that EPA also should not use lack of essentiality as a criterion for cancelling pesticides, yet the Agency continues to do so in connection with Special Reviews (formerly known as Rebuttable Presumption Against Registration or RPAR).

Guidelines for Registering Pesticides -- EPA has made considerable progress in developing guidelines to inform potential pesticide registrants what the various registration requirements are. Yet, we continue to hear of numerous incidents of chemical companies conducting all the tests and obtaining the data called for in the guidelines, and the Agency delaying registration by adding additional requirements not covered in the guidelines.

Addressing this problem through amendments to the statute is probably not appropriate so we suggest that it be handled in the legislative report that accompanies amendments passed by this Congress.

EPA vs. OSHA Jurisdiction -- FIFRA preempts pesticide exposure standards and regulations to EPA. Some anti-pesticide groups have advocated transfer of jurisdiction regarding pesticides in farm workplaces from EPA to OSHA.

In the early 1970's, a jurisdictional squabble between EPA and OSHA arose with regard to pesticide-treated field reentry standards. The Cotton Council and other farm groups endorsed the obvious statutory authority of EPA. We thought this issue was settled. However, in the last year or so, EPA suggested that FIFRA could be amended so that EPA actions do not preempt OSHA provided that OSHA's actions are not inconsistent. Some labor and environmental groups support at least joint OSHA-EPA authority.

We strongly endorse authority over the farm use of pesticides under FIFRA remaining in EPA rather than being shared with OSHA. Even if the actions by both agencies are consistent, the result will be additional unneeded regulatory burdens on farmers and increased overall Federal costs without upgrading the safety level of farmers and farmworkers.

Use of a Registered Pesticide at Less Than Label Dosage, Concentration or Frequency, or against a Target Pest Not On The Label -- Section 2(ee) of FIFRA provides among other things that:

> "The term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: provided, that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment...."

We know that some groups have proposed changing this language so that if the label specified that "use at less than label dosage (etc.) is prohibited" then it would be a misuse for a farmer to apply a registered product at less than label dosage, etc.

The Cotton Council strongly endorses leaving the language of Section 2(ee) as it is. Some farmers who are good managers are able to use pesticides at lower rates and/or less frequently than specified on labels without sacrificing pest control. Such practices are economically beneficial to the farmer and are environmentally sound. We think the proposed change mentioned above would lead to most labels having statements prohibiting use of lower dosages, etc., because registrants are in the business to sell as much of their products as possible.

Conditional Registration of Pesticides -- Under the current provisions of FIFRA, new pesticide products can be "conditionally" registered if most but not all of the data requirements have been met. Under such registrations, the registrants must commit to generating and submitting the additional data required and provide interim reports to EPA on the progress of the required studies.

Conditional registrations are granted for specified periods. The Agency can, and sometime does, extend the period of a conditional registration when additional time is needed to complete the studies.

Some groups advocate doing away with EPA's legislative authority to register new pesticides conditionally. EPA's authority to conditionally register new pesticides has been extremely helpful to agriculture. Without such authority, we probably would not have available for use today the very important synthetic pyrethroid insecticides.

The National Cotton Council strongly endorses leaving the current FIFRA language on conditional registration as it is.

Inert Ingredients -- The term "inert ingredient" is defined in FIFRA as an ingredient which is not active. We agree with most scientists and others who believe that some inerts have some activity. In addition to the chemical nature of the inert itself, activity of inerts may be influenced by several factors including the active ingredient with which it is used, the formulation of the pesticide product, and the conditions (temperature, etc.) under which the product is used.

The National Cotton Council supports new FIFRA language that provides EPA a broad but flexible authority to focus on those inerts for which there are valid reasons to believe they pose a significant risk to health or the environment. Through publication in the *Federal Register* and by other means, users and other groups as well as registrants should be made aware of the inerts that the Agency focuses on. We do not think it is necessary, scientifically logical, or practical for the law to specify how many or how few inert ingredients must be on a priority list.

Pesticide Residue Action Levels -- A decision by the U.S. Circuit Court of Appeals for the District of Columbia in recent years raises doubt about EPA's authority to set pesticide residue action levels. The Court said that the Federal Drug Administration (FDA) had no authority to set action levels for aflatoxin, a naturally occurring toxin, in corn and other commodities. It further said that FDA is statutorily required to establish tolerances through the formal process.

We feel strongly that both FDA and EPA need authority to set action levels. There are several situations where pesticide tolerances are not appropriate and where EPA has set needed action levels.

The National Cotton Council favors amending FIFRA to make it clear that EPA has the statutory authority to set pesticide action levels when they are more appropriate than tolerances.

Private Right of Action -- Amending FIFRA to include a "private right-of-action" provision would create a Pandora's box. It would allow any person who felt aggrieved by supposed misuse of a pesticide to bring suit against farmers and ranchers. Instead of enhancing protection under FIFRA, such a provision would encourage law suits. The current remedies under FIFRA and other statutes are adequate.

Congress has considered similar proposals before and had the wisdom to reject them. The Cotton Council urges that such provisions continue to be rejected.

Public Standing to Initiate Cancellation Hearings, Etc. -- We also strongly oppose any new provisions in FIFRA to give the public standing to initiate suspension or cancellation hearings. Our reasons are similar to those we have stated for our opposition to private right-of-action provisions.

Special Reviews, Adjudicatory Hearings and Cancellation Procedures -- EPA has let it be known that it would like for FIFRA to be amended to eliminate adjudicatory hearings and to convert the current public notice and comment period into informal rulemaking.

We agree that cancellation proceedings are often too long and drawn out and that the procedures need to be streamlined. However, because of the serious consequences to farmers and ranchers of the outcome, we favor retaining the current 2-stage process -- (1) public notice and comment and (2) adjudicatory process.

Indemnification and Disposal -- When EPA suspends and later cancels registration of a pesticide, the Agency is required by law to indemnify owners of existing stocks and to pay for disposal of those stocks.

We support keeping such statutory requirements. The indemnification provision serves as a cost constraint on any precipitous cancellation of pesticide based on inadequate information. Farmers and ranchers who have existing stocks on hand, however, should have the option of using them for labeled uses unless it can be shown that health or environmental risks through such use would be too great.

Pesticide Standards to Protect Workers and Others -- We are strongly in favor of adequate workable standards which promote safe pesticide application and use. We oppose careless and irresponsible application and use that could endanger the health and property of persons in and around pesticide treated fields.

EPA has plenty of authority under the present FIFRA language to promulgate adequate regulations to protect farmworkers and others. There is no need for amendment to the statute in regard to buffer zones, notification requirements, etc.

Public Right-to-Know -- The cotton industry fully supports the idea of sharing health, safety and environmental data with the public. Farmers, like other segments of the public, want this information also.

We are not sure if this issue of public right-to-know should be covered in the statute or in committee report language. We feel, however, that the system for gathering and distributing the information should be as simple and inexpensive as possible. It is suggested also that states have a role in distributing the information.

Risk and Benefit Assessments in General: Who Should Make Them? -- We think that almost everyone agrees that EPA should be the primary party for making risk assessments of pesticides. Congress wisely charged the Agency with this responsibility. Most people also feel that registrants and others should have the right-of-rebuttal to the risk assessment. We strongly support this right.

When it comes to benefits assessment, we feel that EPA is not as well qualified to make such assessments. This concern has been magnified by what we have seen taking place the last few years.

The U.S. Department of Agriculture and state agricultural institutions are better staffed to make benefit assessments of agricultural pesticides. In the last few years, EPA has been using these agencies less and less. Instead, it is depending more and more on its own staff to gather the information and make the assessments.

We can only assume that the Agency has had to expand its staff of agricultural economists, agronomists, entomologists, plant pathologists, weed scientists, engineers, etc., in order to carry this out in-house.

Even with an expanded staff, EPA does not, and probably cannot, do as good a job on benefit assessments as can be done by USDA and the state universities. Within the past two years, EPA management requested Cotton Council technical staff to review a draft benefits assessment document developed within the Agency on an important cotton pesticide being considered for Special Review. The request came about because the internal draft document showed minimal benefits from use of the particular pesticide yet management was picking up information from farmers in various parts of the Cotton Belt about how important and beneficial it was.

As far as we know, EPA has yet to ask USDA and the states to assess the benefits of using this pesticide on cotton.

In the late 1970's, when EPA initiated its rebuttable presumption against registration or RPAR program (now called Special Review), a National Agricultural Pesticide Impact Assessment Program (NAPIAP) was started in USDA. Each year since, Congress has appropriated a sizeable sum of money earmarked for NAPIAP. Some of this money is used by USDA and some of it goes to the states. There is obvious duplication of staff and effort if EPA does not use this highly qualified group of scientists, but instead maintains its own separate staff.

We suggest that FIFRA be amended to provide that USDA in cooperation with the states has the primary responsibility to prepare pesticide benefit assessments and direct EPA formally to request such assessments when one is needed for a particular pesticide or class of pesticides in connection with Interim Administrative Reviews, Special Reviews or Cancellation Proceedings.

EPA should have the right-of-rebuttal in regard to the benefit assessments. Of course, this means that the Agency must have a small well-trained cadre of technical people -- economist, entomologist, agronomist, etc. It should not take nearly as large a staff, however, as is required if EPA has the primary responsibility for making the assessments.

Rereview and Data-Call-In -- One of our biggest immediate concerns is the threat of losing numerous older pesticide products that are still valuable in cotton production.

Under its reregistration program, EPA, as it should, is reviewing its data files on older registered products. Then the Agency proceeds with data-call-in by notifying registrants as to what additional data they must generate and submit in order for the data files to be brought up-to-date with the registration requirements under which new pesticides have been registered. In most cases, this means large financial and manpower commitments by the registrants over a period of 2-3 years to conduct the studies necessary to generate the additional data. If a registrant fails to supply, or show intent to supply by developing appropriate protocols and initiating required studies, EPA suspends registration of the product.

The seriousness of the problem arises from the fact that patents have expired on many of these older products and many of the registrants are small businesses. Not having proprietary rights, these registrants are, understandably, reluctant to spend huge sums of money to save such products without having any market protection. Even if they make the commitment, it might be for naught if the data generated doesn't satisfy EPA.

Notices of intent to suspend under this program have already been issued for several important older cotton pesticides.

Mr. Chairman and members of this Committee, we are seeking help and advice on how to minimize the impact of this on agriculture.

In closing, we want to express appreciation for the opportunity to provide our views on FIFRA matters to the Committee.

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Lieutenant Governor
Leo McCarthy
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July 28, 1987

The Honorable Patrick Leahy
Chairman, Senate Agriculture Committee
638 Dirksen Senate Office Building
Washington D.C. 20510

Dear Senator Leahy:

I am writing to express my strong support for the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with full retention of state authority to regulate pesticides.

Because other environmental and health laws exempt or ignore pesticides, agricultural intensive states such as California rely on FIFRA's minimum standards to establish safeguards. In the wake of severe Reagan Administration cuts in environmental and health protection programs states' ability to set their own standards is vital.

Disintegrating protection at the federal level has prompted the California Legislature and the state's citizens to enact an impressive array of laws including the Birth Defect Prevention Act of 1984 and the Safe Drinking Water and Toxic Enforcement Act of 1986. Our ability to protect people from the threat of exposure to dangerous chemicals is now threatened by the pesticide industry's attempts to pre-empt state authority.

I urge the Senate Agriculture Committee to fight such amendments and preserve the integrity of this legislation.

A decisive victory over these latest attempts to erode FIFRA will not only avoid setting a disasterous precedent for other environmental legislation, but also will allow us to move forward with strategies to strengthen and expand the nation's only pesticide control law.

Occupational safety, particulary among farmworkers, appropriate legal recourse for citizens adversely affected by pesticides, and incentives for innovative and effective pest control technologies are among the issues we must address in a society that uses 2.6 billion pounds of pesticides each year.

Also, any impediments to effective enforcement of FIFRA due to antiquated indemnification language or reliance on cost-benefit rather than health-based standards must be removed.

The committee has the opportunity to make a real difference in the lives of the people of this nation. There can be no higher goal than preventing the poisoning of future generations.

Sincerely,

Leo McCarthy

Leo McCarthy

cc: Senate Agriculture Committee

STATEMENT OF
RONALD L. DEZEMBER
PRESIDENT, LESCO, INC.
SUBMITTED TO
SENATE COMMITTEE ON
AGRICULTURE, NUTRITION AND FORESTRY
U.S. SENATE
JANUARY 7, 1[illegible]

I am Ronald L. Dezember. I am President of Lesco, Inc., which is located in Rocky River, Ohio. I am also chairman of the Home, Lawn, Garden and Turf Committee of the Chemical Producers and Distributors Association.

I greatly appreciate the opportunity to submit these comments as part of the official hearing record on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). I am particularly pleased that Sen. Patrick Leahy (D-Ver.), Chairman of the Senate Committee on Agriculture, Nutrition and Forestry, reopened the hearing record for additional comments.

On behalf of those companies interested in issues affecting the lawn, garden and turf industries, I would like to comment on S. 1524, the Authority of Local Governments Under FIFRA, and discuss the roles of states and their political subdivisions in regulating the sale and use of pesticides and the notification of use of pesticides.

We in the lawn, garden and turf industries strongly oppose S. 1524, the Authority of Local Governments Under FIFRA, introduced by Senators John Chafee (R-R.I.), David Durenberger (R-Minn.) and Robert Stafford (R-Ver.) on July 22, 1987. We support the decision of the U.S. Court of Appeals for the Fourth Circuit when it ruled on June 16, 1987, in the case of the *Maryland Pest Control Association versus Montgomery Country, Maryland*, that FIFRA preempts and invalidates local action to regulate the sale and use of pesticides. We respectfully urge that S. 1524 not be included in any package of FIFRA amendments by this Committee. In particular, we would find it necessary to oppose *any* FIFRA legislation that incorporates a bill such as S. 1524. We face a potentially devastating situation in which nearly 80,000 jurisdictions might have an opportunity to regulate the sale and use of pesticides or notification of use of pesticide. Potential regulatory action by local jurisdictions could create havoc in interstate and intrastate commerce, could result in the public being denied use of safe and effective products and could result in a devastating economic ripple effect across the economy, resulting in a loss of jobs and markets.

The issue of pesticide regulation by local jursidictions -- cities, counties, townships -- is highly controversial. We have been strong advocates of an amendment *to explictly preempt* local jurisdictions from all pesticide regulation authorities, including notification. Local pesticide regulations inappropriately deny the pesticide user -- and the public -- the benefits of pest control. Local jurisdictions simply are not equipped to make the scientific decisions required to validly regulate pesticides. When regulations are based on fear, hysteria and other unscientific grounds, the resulting lost benefits from being denied the use of pesticides are unwarranted.

The Problem: Local Jurisdictions Take Action in the 1980s:

During the 1980s, there have been a proliferation of pesticide restrictions promulgated by counties, townships, and boroughs in at least 15 states. These restrictions range from banning specific pesticides to requiring permits and notification to even attempting to ban all use of pesticides in a specific area. In most cases, these local jurisdictions are ill-equipped to make the scientific assessments necessary to support proper decisions on pesticide use. Without a sound scientfic basis, these local restrictions can create unnecessary and unwarranted hardships for farmers and foresters and dramatically restrict the ability of homeowners to protect their homes, lawns and gardens from insects and weeds.

Of more than 60 examples, we would like to cite three specific examples to demonstrate that the problem is widespread and diverse.

- In 1984, Lyndhurst, Ohio (a Cleveland suburb) proposed legislation attempting to regulate the use of lawn care pesticides. This proposed law would have required notification of neighbors and posting of signs indicating, for example, that a lawn care company had applied a herbicide for dandelions.

- In July, 1984, Wauconda, Illinois passed a final ordinance regulating a variety of commercial pesticide applications: for control of household insects, for mosquito control, and for lawn care. The provisions of this regulation include: establishing registration and permit requirements; mandating the posting of warning signs (outdoors) or warning decals (indoors) of specific size and message, for 72 hours after application; calling for certain pre-notifications; and imposing up to $500 daily fines for each offense.

- Surfside, Florida passed an ordinance making it unlawful to spray or treat lawns, trees, etc., without proper notice (either orally or in writing) to occupants of abutting properties at least 12 hours prior to application. Upon request, the occupants of abutting properties must be given a list of the active ingredients in the substance to be used. Further, upon completion of the treatment, a sign must be posted for at least three days upon the sprayed property warning the public of that application. The sign itself must be at leasat 12 inches by 12 inches, and headed by the word "Danger" or "Warning" in letters not less than two inches high. Anyone violating one of these provisions could be punished by a $1,000 fine and/or up to 90 days imprisonment.

Restrictions such as these can reduce agricultural and forest productivity, stop termiticide applications to protect buildings, or affect what homeowners may or may not do to their lawns. These local jurisdictions have created considerable hardships on farmers, ranchers, foresters, homeowners, pesticide users and manufacturers. These jurisdictions are, in effect, denying the pesticide user--and the public--the benefits of pest control.

These local restrictions are routinely based on far less scientific evidence than is used at the State and Federal levels. As a result, local regulations are likely to place unnecessary restrictions on beneficial uses of pesticides. If a regulation is properly based on scientific grounds (i.e., a showing that there is an unreasonable risk and the regulation will reduce the risk to reasonable levels), any resulting loss in benefits from pesticide use is unnecessary. When regulations are based on fear, hysteria, or other scientific grounds, however, the resulting lost benefits (e.g., reduced forest productivity or increased risk of termite damage) are unwarranted.

We oppose S. 1524 or any other similar amendment or proposal in this regard for three reasons.

First, we object on the basis that Congressional intent in the passage of the 1972 amendments to FIFRA was to deny authority to local jurisdictions. Second, there are a host of practical, hidden and/or unacknowledged problems inherent in all types of pesticide regulation by local jurisdictions. Third, we question the need--what risk uncontemplated by the EPA or the state lead agency does the local communuity want to protect against?

We also oppose local jurisdictions regulating the notification of use of pesticides in both urban and rural settings. These regulations should be established at the state level.

Notification can take many forms. One county in a New England state contemplated a "notification" regulation which would have required persons dusting their roses to notify everyone within a half of a mile before doing so. Does notification include prior notification, post notification, personal notification, or notification by publication? Then the question arises as to who is to be notified: those immediately adjacent or everyone within a certain radius? Consider, for example, an apartment dweller wishing to spray for a common pest; who must that person notify?

The broad definition of pesticide adds to the potential breadth and confusion. It could require people to post a notice if they sprayed for household insects, applied a disinfectant to the bathroom, dusted roses, or put chlorine in a swimming pool.

FIFRA: Legislative History:

Under Section 24 (A) of FIFRA, Congress extended limited pesticide authority to the states to regulate the sale and use of pesticides. The legislative history clearly demonstrates that Congress did not want to share its authority with local jurisdictions.

When the Senate Committee on Agriculture passed its FIFRA bill in 1972, its accompanying committee report concluded:

> The Senate Agriculture Committee considered the decision by the House Committee to deprive political subdivisions of states and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty states and the federal government provide sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any, local authorities, whether towns, counties, villages or municipalities, have the financial wherewithal to provide necessary expert regulation comparable with that provided by the state and federal governments. On that basis and on the basis that permitting such regulation would be an extreme burden on interstate

> commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the states, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, P. 4008 (1972).

At about the same time, the Senate specifically rejected an amendment that would have allowed local political subdivisions, such as cities, towns, counties, etc., to regulate the sale and use of pesticides. The vote was 71-0.

Although this issue of local authority has been frequently discussed in the last 16 years, the Congress has never taken steps to amend FIFRA or alter the legislative history of the issue. In fact, the Senate Committee on Agriculture, Nutrition and Forestry took great pains in 1986 not to alter the legislative history. Thus, after almost two decades, the legislative history of FIFRA has clearly and consistently reflected that only the federal and state governments, not local political subdivisions, should regulate sale and use of pesticides.

Local Jurisdiction Creates Inherent Difficulties and Inequities:

Legislation granting local jurisdictions the authority to regulate the sale and use of pesticides would create serious difficulties and inequities in the use of legally registered and much needed pesticides in this country. The judicious use of pesticides is vital to protect the nation's safety and productiveness. Local pesticide regulations could affect pesticide use in lawn care, tree service, right-of-way maintenance for utilities and railroads, swimming pool maintenance and possibly even agriculture, forestry and home gardens. An example will illustrate the inherent difficulties and inequities of local pesticide regulation.

Railroads and utilities use herbicides to maintain rights-of-way which cut across many local jurisdictions. Even though these applications are done in full compliance with federal and state law, some local jurisdictions have begun to regulate these applications. If this trend continues--as this legislation (S. 1524) virtually assures it will--a single right-of-way maintenence job would need to comply with literally hundreds of local regulations.

Federal and State Risk Assessment Void Need for Local Jurisdictions to Regulate Pesticides:

Nowhere has anyone adequately explained the need for local jurisdictions to regulate pesticides under FIFRA. What goes unprotected except for the intervention of such ordinances? And what is the magnitude of the risk? Have EPA and the states been negligent in not identifying and reducing this risk? It would seem that, unless a more convincing case can be made, the extensive system of state and federal pesticide legislation and regulation is more than adequate to deal with whatever problems arise.

Although local jurisdictions are simply not equipped to make scientific and regulatory decisions required to validly regulate pesticides, federal and state government have the expertise and experience to make the scientific and technical assessments concerning the risks and benefits of the pesticides.

Federal law and EPA regulations and guidelines spell out quite specifically the requirements that must be met before pesticides can be put on the market. An application for registration may include thousands of pages of research data. This data is then examined carefully, using prescribed criteria, by government scientists. The entire process of putting a chemical on the market can take anywhere from five to nine years at a cost of $30 million to $50 million. These are procedures that have evolved over many years with the express purpose of assuring that such a chemical will not cause unreasonable adverse effects to either people or the environment.

In addition, there are Federal laws and regulations that detail how and, in many cases, by whom, a product must be handled and applied. Any deviation from the instructions on a pesticide label, except where provided for by FIFRA and EPA regulations, subjects the violator to civil, and possibly criminal, penalties.

These laws were passed and amended, and these regulations proposed and revised, in order to protect people and the environment, while still allowing farmers and others to produce more economical and higher quality food, feed and fiber, and the homeowner and the government to protect private and public property from destruction by insects, diseases and weeds.

Despite Court Decisions Invalidating Local Pesticide Regulations, There is Need for New Legislation:

A small number of state courts have upheld cases challenging local pesticide regulations on the basis of Federal or state preemption. Several of these cases are discussed below. Without specific statutory language preempting local regulation, however, these decisions remain too few to discourage the flood of local regulation.

The Massachusetts Superior Court overturned the pesticide regulations of the Town of Wendell because of Federal and state preemption. Wendell's regulation would have required approval by the Board of Health of any non-agricultural non-domestic use of a pesticide. Someone wishing to apply a pesticide would be required to submit a request accompanied by information about the prospective use. After a public hearing, the Board of health would grant the request or place restrictions on the use. In a March 19, 1984 decision, Justice Hayer stated that:

> The Pesticide By-Law purported to be enacted by the Town of Wendell at Town Meeting on May 9, 1981 (the By-Law) is null and void and invalid because the By-Law is preempted in its entirety by the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136-136YY, and the Massachusetts Pesticide Control Act, G.L.C. 132B.

Similarly, in New York, municipal pesticide ordinances were invalidated on the grounds that either the Federal law or state law, which were not in harmony with local regulations, preempted the field. Long Island Pest Control Association v. The Town of Huntington, 341 N.Y.S. 2d 93 (1973), affirmed, 351 N.Y.S. 2d 945 (1974).

In July 1987, an Illinois court handed down a decision on the issue of pesticide regulation by local jurisdictions. The Supreme Couart of Illinois held that two state pesticide laws so comprehensively regulated the use of pesticides that the village of Wauconda was preempted from enacting its ordinance regulating the use of pesticides, Pesticide Public Policy Foundation v. The Village of Wauconda, Docket No. 63297.

In June 1987, the U.S. Court of Appeals for the Fourth Circuit handed down its decision in Maryland Pest Control Association v. Prince George's and Montgomery Counties, Maryland, Nos. 86-3633 and 86-3639, June 16, 1987. In that decision, the Court upheld the decision of the lower court that "the legislative history [of FIFRA] indicated that Congress intended to restrict authority to regulate to states and not extend it to their political subdivisions."

Given the wisdom of the holdings in these cases, one might question the need for new legislation. The number of these holdings remain few, however, because the time and expense to fight such a battle rarely seems worthwhile to state attorneys general. Similarly, in light of the relatively few pesticide applicators and users involved in any given local jurisdiction, the litigation costs seem out of proportion to the relatively small market being protected. Indeed, relative to the number of local pesticide regulations, there have been few lawsuits challenging such regulations. The suits which have been brought frequently revolve around state preemption of local jurisdictions because: (1) the state courts look to state law first in solving a problem; and (2) because FIFRA does not contain specific statutory language preempting local regulation. Even if the problem of local pesticide regulation could be put to rest on the basis of state preemption, such a task would require that lawsuits be brought in all 50 states. Making the federal preemption concept more explicit would discourage local regulation by making it easier to challenge those regulations.

In sum, legislation is needed to clarify the federal preemption of local pesticide regulation because some courts: (1) have not acted on the Congressional intent to preempt local pesticide regulation; and (2) have misinterpreted the legislative history to be unclear on the issue of federal preemption of local pesticide regulation.

Solution:

We in the lawn, garden and turf industries favor an amendment to Section 24 (A) of FIFRA to prevent local jurisdictions from regulating the sale and use of pesticides. With this amendment included, Section 24 (A) would read as follows: "A State, but no political subdivision of a state, may regulate the sale and use of any federally registered pesticide..."

We believe that such an amendment to FIFRA would address the problem of local pesticide regulations in the 1980s in the historical context of FIFRA's legislative history, as well as to restore the proper authority to the federal and state governments to jointly regulate the sale and use of pesticides and the notification of use of pesticides.

The congressional track record and recent court decisions, we believe, made it abundantly clear that political subdivisions below the state level should not be involved in regulating the sale or use of pesticides.

Conclusion:

We in the lawn, garden and turf industries greatly appreciate the oppportunity to submit this statement to the Committee and look forward to working with you to help resolve some of the complex and controversial aspects of amendments to FIFRA.

II

100TH CONGRESS
1ST SESSION

S. 1516

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 21 (legislative day, JUNE 23), 1987

Mr. LEAHY (for himself, Mr. LUGAR, Mr. PROXMIRE, and Mr. DECONCINI) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

---

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Reform of 1987".

(b) TABLE OF CONTENTS.—The table of contents is as follows:

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SEC. 2. REFERENCES TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

TITLE I—DEFINITIONS

SEC. 101. APPLICATOR.

Subsection (e) of section 2 (7 U.S.C. 136(e)) is amended to read as follows:

"(e) APPLICATOR.—

"(1) COMMERCIAL APPLICATOR.—

"(A) Except as provided in subparagraph (B), the term 'commercial applicator' means a person (whether or not the person is a private applicator with respect to some uses) who—

"(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use;

"(ii) uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the business or work of the person; or

"(iii) as an employee of a person described in clause (ii), uses or supervises the use of any pesticide.

"(B) The term does not include a person who uses or supervises the use of a pesticide as described in paragraph (2).

"(2) PRIVATE APPLICATOR.—The term 'private applicator' means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity—

"(A) on property owned or rented by such person or the employer of such person; or

"(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

"(3) CERTIFIED APPLICATOR.—The term 'certified applicator' means a commercial or private applicator who is certified under section 4.

"(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if the pesticide is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is used.".

SEC. 102. INGREDIENT STATEMENT.

Subsection (n) of section 2 (7 U.S.C. 136(n)) is amended to read as follows:

"(n) INGREDIENT STATEMENT.—The term 'ingredient statement' means a statement that contains—

"(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in a pesticide;

"(2) the name of each inert ingredient in the pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the toxicity, use pattern, and concentration level of the inert ingredient in the pesticide;

"(3) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic;

"(4) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and

"(5) the name of any inert ingredient for which the Administrator has required additional data under section 3(g)(5) because such ingredient is listed under section 3(g)(1)(A) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under section 3(c)(8).".

SEC. 103. MISBRANDED.

Section 2(q)(1) (7 U.S.C. 136 (q)(1)) is amended—

(1) by striking out "or" at the end of subparagraph (G);

(2) by striking out the period at the end of subparagraph (H) and inserting after the close quotation marks "; or"; and

(3) by adding at the end thereof the following new subparagraph:

"(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label—

"(i) is not written in an appropriate language as required by section 17(a)(3)(A); or

"(ii) does not contain the same health, safety, and hazard precautions as the pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country."

SEC. 104. PESTICIDE.

Section 2(u) (7 U.S.C. 136(u)) is amended—

(1) by striking out "and" before the first clause (2); and

(2) by inserting after "desiccant" the following: ", and (3) any substance or mixture of substances intended for a purpose described in subsection (ff)".

SEC. 105. TO USE ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING.

The first proviso of section 2(ee) (7 U.S.C. 136(ee)) is amended—

(1) in clause (1), by inserting before the comma at the end thereof the following: "unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency"; and

(2) in clause (3), by inserting before the comma at the end thereof the following: "unless the labeling specifically states that the product may be applied only by the methods specified on the labeling".

SEC. 106. ADDITIONAL DEFINITIONS.

Section 2 (7 U.S.C. 136) is amended by adding at the end thereof the following new subsections:

"(ff) ANTIMICROBIAL.—The term 'antimicrobial' means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

"(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surface or in water or air;

"(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

"(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

"(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

"(5) fungicides or fungistats.

"(gg) CONTAINER.—The term 'container' means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding spray applicator tanks) used to enclose a pesticide or pesticide-related waste.

"(hh) OUTSTANDING DATA REQUIREMENT.—

"(1) IN GENERAL.—The term 'outstanding data requirement' means a requirement for any study, information, or data that is necessary to make a determination under section 3(c)(5) and which study, information, or data—

"(A) has not been submitted to the Administrator; or

"(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 3(c)(5) and the regulations and guidelines issued under such section, as determined by the Administrator.

"(2) FACTORS.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

"(ii) PESTICIDE DEALER.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the term 'pesticide dealer' means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or designated under section 8(d)(2).

"(2) EXCEPTION.—Such term does not include a person who only distributes or sells pesticides that are classified for general use and that are not designated under section 8(d)(2).

"(jj) PESTICIDE TESTING FACILITY.—The term 'pesticide testing facility' means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing the pesticide). The term does not include any person solely on account of the participation of such person as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under section 5.

"(kk) TO DISTRIBUTE OR SELL.—The term 'to distribute or sell' means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.".

TITLE II—REGISTRATION OF PESTICIDES

SEC. 201. REQUIREMENT OF REGISTRATION.

Subsection (a) of section 3 (7 U.S.C. 136a(a)) is amended to read as follows:

"(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act.".

SEC. 202. LIMITATION ON UNREGISTERED PESTICIDES.

Section 3(a) (7 U.S.C. 136a(a)) (as amended by section 201 of this Act) is further amended by adding at the end thereof the following new sentence: "To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.".

SEC. 203. DATA COMPENSATION.

Section 3(c)(1)(D)(ii) (7 U.S.C. 136a(c)(1)(D)(ii)) is amended—

(1) by striking out "or for reregistration" and inserting in lieu thereof "for reregistration, or to support the safety of an inert ingredient"; and

(2) by inserting "or in support of the safety of an inert ingredient" before "by any other person".

SEC. 204. DATA COMPENSATION AND ARBITRATION.

Section 3(c)(1)(D) (7 U.S.C. 136a(c)(1)(D)) is amended—

(1) by redesignating clause (iii) as clause (iv); and

(2) by inserting after clause (ii) the following new clause:

"(iii)(I) In the case of a pesticide the term of the patent for which has expired, the terms and amount of compensation, for data that was submitted for such pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data may be fixed before the submission of such application by arbitration under clause (ii) initiated by such person.

"(II) The arbitration shall be binding on the original data submitter and shall be binding on such person after the date the application of such person is submitted.

"(III) No official or court of the United States shall have power or jurisdiction to review any such finding or determination of the arbitrator, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint, with supporting affidavits, attesting to specific instances of such fraud, misrepresentation, or other misconduct.

"(IV) Each party to the first arbitration under this clause to determine the terms and amount of compensation for the use of particular data shall share equally in the payment of the fees and expenses of the arbitrators and shall each pay its own attorney's fees.

"(V) In all subsequent arbitrations under this clause to determine the terms and amount of compensation for the use of such data, the party to such subsequent arbitration who seeks to cite the data of the original data submitter shall pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter.

"(VI) Clause (ii) shall apply to arbitrations under this clause, except as otherwise provided in this clause.".

SEC. 205. DATA IN SUPPORT OF REGISTRATION.

The second sentence of section 3(c)(2)(A) (7 U.S.C. 136a(c)(2)(A)) is amended by inserting "(including information concerning an inert ingredient in a pesticide)" after "paragraph".

SEC. 206. ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATIONS.

Section 3(c)(2)(B) (7 U.S.C. 136a(c)(2)(B)) is amended—

(1) by striking out clauses (i) and (ii) and inserting in lieu thereof the following new clauses:

"(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide or the existing registrations of a group of pesticides, the Administrator shall notify the registrant of each pesticide to which the determination relates and provide a list of such registrants to any person.

"(ii)(I) Each registrant of such a pesticide shall provide evidence within 90 days after receipt of notification that the registrant is taking appropriate steps to secure and submit the additional data that are required.

"(II) Two or more registrants may agree to develop jointly, or to share in the cost of development of, such data. Any registrant who enters into such an agreement, or who offers to agree to share in the cost of development of such data, shall be entitled to examine such data and rely on such data to maintain or obtain registrations under this Act or under the law of any State. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made."; and

(2) in clause (iii), by striking out the first sentence and inserting in lieu thereof the following new sentence: "If at the end of 60 days after two or more registrants have entered into an agreement under clause (ii) the registrants have not further agreed on the terms of the data development or cost-sharing agreement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by the Service.".

SEC. 207. COMPENSATION FOR DATA ON INERT INGREDIENTS.

Subparagraph (D) of section 3(c)(2) (7 U.S.C. 136a(c)(2)(D)) is amended to read as follows:

"(D)(i) No applicant for registration or amended registration of a pesticide who proposes to purchase a registered pesticide from another producer to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

"(I) submit or cite data pertaining to such purchased pesticide; or

"(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data.

"(ii) No applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study concerning such ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.".

SEC. 208. NOTICE OF APPLICATION.

Section 3(c)(4) (7 U.S.C. 136a(c)(4)) is amended—

(1) in the first sentence, by striking out "promptly" and inserting in lieu thereof "not later than 30 days"; and

(2) in the second sentence—

(A) by striking out "The notice" and inserting in lieu thereof "Except as provided in paragraph (9), the notice"; and

(B) by striking out "30" and inserting in lieu thereof "60".

SEC. 209. DENIAL OF REGISTRATION.

Paragraph (6) of section 3(c) (7 U.S.C. 136a(c)(6)) is amended to read as follows:

"(6) DENIAL OF REGISTRATION.—

"(A) If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration—

"(i) of the determination and of the reasons therefor (including the factual basis); and

"(ii) unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide.

"(B) Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the decision of the Administrator and the reasons therefor (including the factual basis). The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor.

"(C)(i) On such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6, except as otherwise provided in this subparagraph.

"(ii) A request for a hearing under section 6 shall be made within 30 days after the receipt of such notification.

"(iii) The Administrator may issue regulations governing the right to a hearing under section 6 with regard to the denial of any application for the registration of a pesticide containing an ingredient that was canceled under section 6. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings.

"(iv) Section 6(g)(2) applies with respect to the publication of a notice of a denial of a registration.".

SEC. 210. REGISTRATION UNDER SPECIAL CIRCUMSTANCES.

The second sentence of section 3(c)(7)(A) (7 U.S.C. 136a(c)(7)(A)) is amended—

(1) by striking out "submit" each place it appears and inserting in lieu thereof "submit or cite";

(2) by striking out "submission" and inserting in lieu thereof "submission or citation"; and

(3) by striking out "submitted" and inserting in lieu thereof "submitted or cited".

SEC. 211. CONDITIONAL REGISTRATION.

Subparagraphs (B) and (C) of section 3(c)(7) (7 U.S.C. 136a(c)(7) (B) and (C)) are amended to read as follows:

"(B)(i) The Administrator may conditionally amend the registration of a pesticide under this subparagraph to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

"(I) the applicant has submitted or cited additional data that the Administrator may require solely for the proposed additional use;

"(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment; and

"(III) the additional use is in the public interest.

"(ii)(I) Except as provided in subclause (II), if the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), no registration of the pesticide may be amended under clause (i) to add any food or feed use during the pendency of any evaluation by the Administrator initiated by such notice.

"(II) If the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), the Administrator may amend the registration of the pesticide under clause (i) to add a minor food or feed use if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is not available an effective alternative pesticide that does not meet or exceed such risk criteria.

"(iii) An applicant seeking an amended registration of a pesticide under this subparagraph shall submit or cite to the Administrator such data as would be required to obtain a registration of a similar pesticide under paragraph (5). Except as provided in clause (iv), if the applicant is unable to submit or cite an item of such data because it has not yet been generated, the Administrator may amend the registration of the pesticide under such conditions as will require the submission or citation of such data not later than the time such data are required to be submitted for the maintenance of a registration of the similar pesticide under this section.

"(iv) If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide and if a period reasonably sufficient for the generation and submission of such data has elapsed since the Administrator first imposed the data requirement, a conditional amendment to permit an additional use of the pesticide for other than a minor use shall not be granted under clause (i) unless such data have been submitted.

"(C)(i) The Administrator may conditionally register a pesticide under this subparagraph containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data that have not been submitted because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement—

"(I) on the conditions that by the end of such period the Administrator receives such data and that the data that the Administrator receives do not meet or exceed risk criteria enumerated in regulations issued under paragraph (8); and

"(II) on such other conditions as the Administrator may prescribe.

"(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

"(I) use of the pesticide during the period referred to in clause (i) will not cause any unreasonable adverse effect on the environment; and

"(II) use of the pesticide is in the public interest.

"(iii) The Administrator shall not conditionally register a pesticide under this subparagraph if—

"(I) data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of such a pesticide under paragraph (5);

"(II) a period reasonably sufficient for generation of such data has elapsed since the Administrator first imposed the data requirement; and

"(III) such data have not been submitted to the Administrator.".

SEC. 212. PUBLIC INTERIM ADMINISTRATIVE REVIEW.

(a) IN GENERAL.—Paragraph (8) of section 3(c) (7 U.S.C. 136a(c)(8)) is amended to read as follows:

"(8) PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

"(A) A public interim administrative review process to determine whether the use of a pesticide (including a category of pesticides) may cause unreasonable adverse effects on the environment shall be conducted in accordance with this paragraph.

"(B)(i) Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

"(ii) Such criteria shall be established on the basis of levels of risk and may include consideration of currently available exposure data.

"(iii) Absence of exposure data shall not delay or preclude initiation of a public interim administrative review. The Administrator may decline to initiate a public interim administrative review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

"(C) The Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of such pesticide required under this Act unless such public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

"(D)(i) On receipt of information respecting a pesticide demonstrating that the criteria for initiating a public interim administrative review established under subparagraph (B) have been met, the Administrator shall immediately notify all registrants of such pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met.

"(ii) Not later than 30 days after receipt of a notice provided under clause (i), a registrant may respond to such notice.

"(iii) Not later than 60 days after the Administrator provides a notice under clause (i) concerning a pesticide, the Administrator shall determine whether a public interim administrative review of the pesticide shall be initiated.

"(E) If the Administrator intends to initiate a public interim administrative review of a pesticide that is registered for agricultural uses, the Administrator shall notify the Secretary of Agriculture of the intention to initiate such review and the reasons therefor.

"(F)(i) Any public interim administrative review proceeding shall be initiated and conducted in accordance with regulations published by the Administrator. Such regulations shall provide that a public interim administrative review shall include—

"(I) a notice of initiation of the public interim administrative review and opportunity for public comment on such notice;

"(II) a notice of a preliminary determination and opportunity for public comment on such notice; and

"(III) a notice of a final determination, except that such regulations may authorize the Administrator to combine or forgo any such notice.

"(ii) Any proposed determination of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at its next scheduled meeting for comment solely on relevant scientific issues. The public may submit comments to the Scientific Advisory Panel concerning such issues.

"(iii)(I) The notice of the initiation of a public interim administrative review or the notice of a preliminary determination shall state the basis for such review or determination and include a request for any additional data needed and a bibliography of all scientific data and studies and expert analyses concerning the risks or benefits of the pesticide that are under review.

"(II) Information in the bibliography shall be made available to the public consistent with section 10. The Administrator shall determine, to the extent feasible, before the initiation of the public interim administrative review which data in the bibliography may be disclosed to the public under section 10(d)(1).

"(III) If the Administrator receives additional data concerning such risks or benefits, the Administrator, within 30 days after receiving the additional data, shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

"(iv)(I) Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments may be submitted on such review or determination. Any person who submits comments shall disclose to the Administrator all scientific data and studies and expert analyses in the possession of such person concerning the risks or benefits of the uses of the pesticide that are under review that were not included in the bibliography included in such notice.

"(II) If such person receives additional scientific data or studies or expert analyses of such data or studies that were not included in such bibliography, the person shall disclose such scientific data, studies, and expert analysis to the Administrator within 30 days after receipt.

"(v) Not later than 18 months after the initiation of a review, the Administrator shall decide which regulatory action (if any) to take regarding the pesticide that is the subject of the review and shall publish the decision.

"(vi) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

"(I) additional data critical to a fair and accurate determination of risks posed by the pesticide subject to review are required;

"(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year; and

"(III) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for such data at such time.

"(G) Any person may seek judicial review under section 16(a) of the failure of the Administrator to act within the time period prescribed under this paragraph.".

(b) APPLICATION OF AMENDMENT.—The amendment made by subsection (a) shall apply to public interim administrative reviews under section 3(c)(8) of the Federal Insecticide, Fungicide, and Rodenticide Act initiated after January 1, 1988.

SEC. 213. PREREGISTRATION ACCESS TO DATA.

Section 3(c) (7 U.S.C. 136a(c)) is amended by adding at the end thereof the following new paragraph:

"(9) PREREGISTRATION ACCESS TO DATA.—

"(A) If an application for—

"(i) a registration of a pesticide containing a new active ingredient; or

"(ii) a registration of a pesticide to authorize the initial food use of a pesticide active ingredient,

is submitted to the Administrator, the Administrator, before acting on such application, shall provide, in accordance with this paragraph, public access to health, safety, and environmental data that are submitted or cited in support of such application.

"(B) To obtain access to the data referred to in subparagraph (A), a person shall send by certified mail—

"(i) not later than 30 days after the publication under paragraph (4) of a notice of the application referred to in subparagraph (A); and

"(ii) simultaneously to the Administrator and to the applicant for the registration of the pesticide,

a request for such access and the affirmation required by subparagraph (D).

"(C)(i) Unless within 15 days after the receipt by the Administrator of a request for access to such data and of an affirmation complying with subparagraph (D) the applicant submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and the reasons for the objection, the Administrator shall grant the request. If an objection to a request is submitted to the Administrator within such 15-day period, the Administrator shall determine whether to grant the request within 5 days after the receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the applicant making the objection has been notified that access has been granted.

"(ii) If access to data is denied under clause (i), comments on the application for which such data were submitted or cited shall be filed within 60 days after the decision of the Administrator denying access.

"(D)(i) Data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) containing the information prescribed by clause (ii).

"(ii) The affirmation required under clause (i) shall—

"(I) state that the person is not engaged in, and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate thereof engaged in, the production, sale, or distribution of a pesticide;

"(II) identify any business, employer, or other person, if any, on whose behalf the person is requesting access to the data; and

"(III) state that the person will not intentionally or recklessly violate this paragraph.

"(iii) For purposes of clause (ii), an affiliate of a person is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the other person.

"(iv) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

"(E)(i) Data supporting an application may be made available under subparagraph (A) to a person only for the purpose of permitting the person to comment to the Administrator on such application. Such comments may reasonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

"(ii) Except as provided in clause (iii), a person who obtains data under subparagraph (A) (directly or indirectly) may not—

"(I) publish, copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world; or

"(II) use the data for any purpose in any court or agency of the United States or any State or political subdivision thereof before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

"(iii) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide for which such data were submitted.

"(F)(i) Data made available under this paragraph may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by this paragraph and may not be removed from such office.

"(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent to the data submitter on request.

"(G) Once access to data respecting an application is granted, the data may be examined and notes may be taken for use in developing comments on the application. Such comments on the application shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator for an additional 30 days for good cause.".

SEC. 214. CLASSIFICATION OF PESTICIDES.

Section 3(d)(1) (7 U.S.C. 136a(d)(1)) is amended—

(1) in the second sentence of subparagraph (A), by striking out "on the initial classification"; and

(2) in subparagraph (C)—

(A) by striking out the colon preceding clause (i) and inserting in lieu thereof a period;

(B) by striking out clause (i);

(C) by striking out "(ii)"; and

(D) by running in the material after "restricted use." so that the margin is the same as the margin of paragraph (1)(C).

SEC. 215. PRIORITY LIST AND DATA REQUIREMENTS.

Subsection (g) of section 3 (7 U.S.C. 136a) is amended to read as follows:

"(g) PRIORITY LIST AND DATA REQUIREMENTS FOR INERT INGREDIENTS.—

"(1) ESTABLISHMENT OF LIST.—

"(A) Subject to paragraph (4), the Administrator shall establish a priority list of inert ingredients consisting of—

"(i) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8);

"(ii) inert ingredients—

"(I) for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment;

"(II) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect; and

"(III) that have significant use in pesticides or to which there is significant exposure from pesticides; and

"(iii) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment and to which there is significant exposure from pesticides.

"(B) In establishing the priority list, the Administrator may take into account—

"(i) the differences in concept, usage, and environmental risk between various classes of pesticides; and

"(ii) data for evaluating such risk between agricultural and nonagricultural pesticides.

"(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of this subsection, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

"(3) JUDICIAL REVIEW.—The priority list under paragraph (1), the inclusion or exclusion of an ingredient on or from the priority list, and any revision of the priority list shall not be subject to judicial review.

"(4) NUMBER OF INGREDIENTS.—The priority list under paragraph (1) shall consist of not less than 50 inert ingredients unless the Administrator determines that there is not a sufficient number of inert ingredients meeting the requirements for listing under paragraph (1) to reach such minimum number. Such list may not exceed 75 inert ingredients.

"(5) ADDITIONAL DATA.—

"(A)(i) The Administrator shall determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list under paragraph (1).

"(ii) The Administrator shall require submission of such data from each registrant of such pesticide under this Act or from manufacturers and processors of the inert ingredient under the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

"(iii) Such data shall be submitted within a reasonable time but not later than 4 years after the date of the request. The Administrator may extend the period for the submission of data by not more than 2 years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the necessary data.

"(B) Data requirements imposed under subparagraph (A) or a decision not to require data for an inert ingredient shall be subject to judicial review under section 16(b).

"(6) EVALUATION.—Within 1 year after the receipt of additional data under paragraph (5) for an inert ingredient, the Administrator shall evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment caused by pesticides containing such inert ingredient. Under exceptional circumstances, the Administrator may extend the period for evaluation by not more than 1 year.

"(7) CONSTRUCTION.—This subsection shall not be construed to affect the authority of the Administrator—

"(A) to regulate under this Act impurities, contaminants, degradants, or other ingredients of pesticides that have not been deliberately added to the pesticides;

"(B) to regulate under this Act any deliberately added inert ingredient that has not previously been used in a pesticide or a significant new use in a pesticide of a deliberately added inert ingredient;

"(C) to require the submission of short-term, environmental fate, or residue studies for deliberately added inert ingredients; or

"(D) to require the submission of revised formula statements under subsection (c)(2)(B).".

SEC. 216. ANTIMICROBIAL STANDARDS.

(a) GENERAL.—Section 3 (7 U.S.C. 136a) is amended by adding at the end thereof the following new subsection:

"(h) ANTIMICROBIAL STANDARDS.—

"(1) STANDARDS.—The Administrator shall—

"(A) establish efficacy standards for antimicrobial control agents (including disinfectants) used to control pest microorganisms that pose a threat to human health, including standards for disinfectants used in hospitals and other health care facilities;

"(B) conduct, or require to be conducted, representative monitoring (including testing) of the compliance of the agents with the standards; and

"(C) implement an enforcement program under which the agents must comply with the standards or be prohibited from sale or distribution as an antimicrobial agent.

"(2) DEFINITION.—As used in paragraph (1), the term 'efficacy' means the capacity of an antimicrobial control agent (including a disinfectant) to produce the desired effect or the effectiveness of such an agent.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 60 days after the date of enactment of this Act.

SEC. 217. NEUROTOXICOLOGICAL AND BEHAVIORAL EFFECTS TESTING.

Section 3 (7 U.S.C. 136a) (as amended by section 216 of this Act) is further amended by adding at the end the following:

"(i) NEUROTOXICOLOGICAL AND BEHAVIORAL EFFECTS TESTING.—The Administrator shall—

"(1) develop methods for testing to accurately detect neurotoxicological and behavioral effects of pesticides, and their ingredients; and

"(2) as such methods are developed, require to the extent appropriate and necessary, that data from such testing be submitted by persons seeking to obtain or maintain pesticide registrations.".

TITLE III—REREGISTRATION OF REGISTERED PESTICIDES

SEC. 301. REREGISTRATION OF REGISTERED PESTICIDES.

The Act is amended by inserting after section 3 (7 U.S.C. 136a) the following new section:

"SEC. 3A. REREGISTRATION OF REGISTERED PESTICIDES.

"(a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

"(1) there are no outstanding data requirements; and

"(2) the requirements of section 3(c)(5) have been satisfied.

"(b) SPECIAL AUTHORITIES OF ADMINISTRATOR.—

"(1) GUIDELINES.—

"(A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in accordance with subsection (f)(1) in—

"(i) summarizing studies;

"(ii) reformatting studies;

"(iii) identifying adverse information; and

"(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section.

"(B) Guidelines issued under this paragraph shall not be subject to judicial review.

"(2) MONITORING.—The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under this section.

"(3) SUSPENSIONS AND PENALTIES.—

"(A) The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if—

"(i) the Administrator determines that progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under subsection (e)(3)(B) or (f)(1)(H) within the time period prescribed by subsection (e)(4)(B) or (f)(2)(B) or the registrant has not submitted such data to the Administrator within such time period;

"(ii) the Administrator determines that tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under subsection (g)(1)(B);

"(iii) the Administrator determines that progress is insufficient to ensure submission of the data referred to in clause (ii) within the time period prescribed by subsection (g)(2)(B) or the required data have not been submitted to the Administrator within such time period; or

"(iv) a registrant fails to comply with clause (ii) or (iii) of section 3(c)(2)(B).

"(B) A registrant who submits a certification under subsection (f)(1)(G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

"(c) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

"(1) The first phase shall include the listing under subsection (d) of the active ingredients of the pesticides that will be reregistered.

"(2) The second phase shall include the submission to the Administrator under subsection (e) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

"(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (f).

"(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (g) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

"(5) The fifth phase shall include the review by the Administrator under subsection (h) of data submitted for reregistration and appropriate regulatory action by the Administrator.

"(d) PHASE ONE.—

"(1) PRIORITY FOR REREGISTRATION.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section) that—

"(A) are in use on or in food or feed and may result in postharvest residues;

"(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

"(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

"(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

"(2) REREGISTRATION LISTS.—For purposes of reregistration under this section, the Administrator shall by order—

"(A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registration standards have been issued before such date;

"(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

"(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

"(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

"(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

"(4) NOTICE TO REGISTRANTS.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (e) whether the registrants intend to seek or not to seek reregistration of such pesticides.

"(e) PHASE TWO.—

"(1) IN GENERAL.—The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

"(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

"(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

"(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

"(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

"(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

"(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

"(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

"(iii) data identified under clause (i) that have not been submitted to the Administrator; and

"(B) either—

"(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

"(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (f)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

"(4) TIME PERIODS.—

"(A) A submission under paragraph (2) or (3) shall be made—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

"(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(5) CANCELLATION AND REMOVAL.—

"(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

"(B)(i) If—

"(I) no registrant of a pesticide containing an active ingredient listed under subsection (d)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

"(II) no such registrant complies with paragraph (3)(A);

"(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A); or

"(IV) the fee prescribed by subsection (j)(1) has not been paid with regard to the active ingredient, the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (d)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

"(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

"(I) during the comment period a person acquires the rights of the registrant in that registration;

"(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

"(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by subsection (j)(1) has been paid.

"(f) PHASE THREE.—

"(1) INFORMATION ABOUT STUDIES.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) who has submitted a notice under subsection (e)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under subsection (b)(1), to the Administrator—

"(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section;

"(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

"(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

"(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

"(E) an identification of data that are required to be submitted to the Administrator under section 6(g)(4) indicating an adverse effect of the pesticide;

"(F) an identification of any other information available that in the view of the registrant supports the registration;

"(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

"(H) either—

"(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

"(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

"(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

"(2) TIME PERIODS.—

"(A) The information required by paragraph (1) shall be submitted to the Administrator—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

"(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(3) CANCELLATION.—

"(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

"(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

"(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

"(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

"(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

"(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

"(g) PHASE FOUR.—

"(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQUIREMENTS.—

"(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (e)(3) and (f)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (f)(1).

"(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

"(2) TIME PERIODS.—

"(A) The Administrator shall take the action required by paragraph (1)—

"(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

"(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

"(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

"(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

"(h) PHASE FIVE.—

"(1) DATA REVIEW.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (d)(2) and of all other available data found by the Administrator to be relevant.

"(2) REREGISTRATION AND OTHER ACTIONS.—

"(A) Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (g), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year.

"(B) Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission. The Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

"(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

"(D) If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

"(i) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (e), (f), (g), or (h) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

"(j) FEES.—

"(1) ANNUAL REREGISTRATION FEES.—During the 5-year period beginning on the first day of the first calendar year following the date of enactment of this section, the registrants of pesticides that contain an active ingredient that is listed under subsection (d)(2) shall collectively pay an annual fee of—

"(A) $150,000, in the case of an active ingredient that—

"(i) is contained in pesticides that collectively generate annual gross revenue for their registrants of $10,000,000 or more; and

"(ii) was contained in any pesticide first registered before October 1, 1978;

"(B) $75,000, in the case of an active ingredient that—

"(i) is contained in pesticides that collectively generate annual gross revenue for their registrants of $10,000,000 or more; and

"(ii) was not contained in any pesticide first registered before October 1, 1978;

"(C) $20,000, in the case of a pesticide active ingredient that—

"(i) is contained in pesticides that collectively generate annual gross revenue for their registrants of less than $10,000,000; and

"(ii) was contained in any pesticide first registered before October 1, 1978; and

"(D) $10,000, in the case of a pesticide active ingredient that—

"(i) is contained in pesticides that collectively generate annual gross revenue for their registrants of less than $10,000,000; and

"(ii) was not contained in any pesticide first registered before October 1, 1978.

"(2) PAYMENT DATE.—Each annual fee prescribed by paragraph (1) shall be due and payable on June 30th of each year during the 5-year period described in paragraph (1).

"(3) OTHER FEES.—On payment of annual fees for the reregistration of a pesticide in accordance with paragraph (1), the Administrator may not levy any other fees for the reregistration with respect to that active ingredient.

"(4) APPORTIONMENT.—

"(A) If two or more registrants are required to pay any annual fee prescribed by paragraph (1) with respect to a particular active ingredient, the annual fee for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the 3 calendar years preceding the date that the annual fee is due and payable.

"(B) The Administrator, by order, may require registrants referred to in subparagraph (A) to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion annual fees under this subsection.

"(C) If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any annual fee prescribed by this subsection for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under this subsection, the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the annual fee is imposed. The Administrator shall reapportion the annual fee among the remaining registrants and notify the registrants that the registrants are required to pay to the Administrator any unpaid balance of the annual fee within 30 days after receipt of such notice.

"(k) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (e), (f), (g), and (j) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

"(l) REREGISTRATION FUND.—

"(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration fund.

"(2) SOURCE AND USE.—All fees collected by the Administrator under subsection (j) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out this section.

"(3) UNUSED FUNDS.—Money in the fund not currently needed to carry out this section shall be—

"(A) maintained on hand or on deposit;

"(B) invested in obligations of the United States or guaranteed thereby; or

"(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(4) ACCOUNTING.—The Administrator shall—

"(A) provide an annual accounting of the fees collected and disbursed from the fund; and

"(B) take all steps necessary to ensure that expenditures of such funds are used only to carry out this section.

"(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).".

TITLE IV—CERTIFIED APPLICATORS

SEC. 401. CERTIFICATION AND TRAINING FOR PESTICIDE APPLICATORS.

(a) IN GENERAL.—Section 4 (7 U.S.C. 136b) is amended by adding at the end thereof the following new subsections:

"(d) USE BY COMMERCIAL APPLICATORS.—

"(1) IN GENERAL.—It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is—

"(A) a certified commercial applicator; or

"(B) a registered commercial applicator under the direct supervision of a certified commercial applicator.

"(2) CERTIFIED COMMERCIAL APPLICATORS.—To be considered to be a certified commercial applicator, a person, at a minimum, shall—

"(A) have met the standards prescribed under subsection (a) and have received training—

"(i) prescribed by the State agency, including training in the material referred to in subsection (g);

"(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

"(iii) that satisfies the minimum standards for training programs prescribed under subsection (h);

"(B) have had field, institutional, or industrial experience in pesticide use and application;

"(C) have passed an examination prescribed by such State agency; and

"(D) possess a valid commercial applicator certification issued by such State agency.

"(3) REGISTERED COMMERCIAL APPLICATORS.—

"(A) To be considered to be a registered commercial applicator, a person, at a minimum, shall—

"(i) have received training—

"(I) prescribed by the State agency, including training in the material referred to in subsection (g); and

"(II) conducted by a trainer who has met the requirements prescribed under subsection (h); and

"(ii) possess a valid registration issued by such State agency.

"(B) A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

"(e) USE BY PRIVATE APPLICATORS.—

"(1) IN GENERAL.—A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if the pesticide is applied by a person who is either—

"(A) a certified private applicator; or

"(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

"(2) CERTIFIED PRIVATE APPLICATORS.—To be considered to be a certified private applicator, a person, at a minimum, shall—

"(A) have met the standards prescribed under subsection (a) and have received training—

"(i) prescribed by the State agency, including training in the material described in subsection (g);

"(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

"(iii) that satisfies the minimum standards for training prescribed under subsection (h); and

"(B) possess a valid private applicator certification issued by such State agency.

"(3) SUPERVISED PRIVATE APPLICATORS.—

"(A) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction—

"(i) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling; and

"(ii) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

"(B) The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A)(i) has been received.

"(f) RECERTIFICATION AND REREGISTRATION.—

"(1) IN GENERAL.—Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the State agency of such State of not more than 5 years.

"(2) TRAINING MATERIAL.—The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14.

"(3) RECERTIFICATION.—To be recertified, an applicator, at a minimum, shall meet—

"(A) the requirements of subparagraphs (A), (B), and (D) of subsection (d)(2); or

"(B) the requirements of paragraphs (1) and (2) of subsection (e).

"(4) REREGISTRATION.—To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

"(g) TRAINING MATERIAL.—

"(1) DEVELOPMENT.—The Administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling.

"(2) REVISIONS.—Within 12 months after the effective date of this section, the Administrator, in consultation with the Secretary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

"(h) MINIMUM STANDARDS FOR TRAINERS AND TRAINING PROGRAMS.—

"(1) TRAINING OF COMMERCIAL APPLICATORS.—

"(A) The Administrator shall establish within 1 year after the effective date of this section—

"(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d); and

"(ii) minimum standards for the training programs referred to in subsection (d).

"(B) Training programs prescribed by any State under subsection (d) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards.

If on expiration of such 90-day period, the training program of the State does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

"(2) TRAINING OF PRIVATE APPLICATORS.—

"(A) The Administrator shall establish within 2 years after the effective date of this section—

"(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e); and

"(ii) minimum standards for the training programs referred to in subsection (e).

"(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period the training program of a State fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards.

If on expiration of such 90-day period the training program of the State does not meet such standards, the Administrator shall prescribe the training programs referred to in subsection (e) for use in such State.

"(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.—A State agency may approve any privately administered training program that the Administrator determines meets the more stringent of—

"(1) requirements established under this section; or

"(2) requirements established by the State agency.

"(j) ENFORCEMENT OFFICER TRAINING.—Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, at a minimum, includes training covering materials specified in subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

"(k) SEPARATE STANDARDS.—In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

"(l) DEFINITION OF STATE AGENCY.—For purposes of this section, the term 'State agency' means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforcement responsibility or that does not have an agency designated under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.".

(b) EFFECTIVE DATES.—

(1) COMMERCIAL APPLICATORS.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), subsection (d) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by subsection (a)) shall become effective in a State on the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (d) are required to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(B) CERTIFIED COMMERCIAL APPLICATORS.—If an applicator in a State is certified as a commercial applicator under subsection (a) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act before the effective date prescribed by subparagraph (A) and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d) of such section, such applicator shall be recertified—

(i) within 2 years after the date the training programs of such State under subsection (d) comply with such minimum standards of the Administrator; or

(ii) within such earlier time as the State may prescribe.

(C) REGISTERED COMMERCIAL APPLICATORS.—The requirements of subsection (d) of section 4 for registered commercial applicators shall become effective 1 year after the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (d) are required to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(2) PRIVATE APPLICATORS.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), subsection (e) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by subsection (a)) shall become effective in a State on the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (e) are required to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under subsection (h).

(B) CERTIFIED PRIVATE APPLICATORS.—If an applicator in a State is certified as a private applicator under subsection (a) of section 4 before the effective date prescribed by subparagraph (A) and the Administrator has determined that the previous certification or recertification requirements in such State do not conform to the requirements of subsection (d) of such section, such applicator shall be recertified—

(i) within 2 years after the date the training programs of such State under subsection (e) comply with such minimum standards of the Administrator; or

(ii) within such earlier time as the State may prescribe.

(C) SUPERVISED PRIVATE APPLICATORS.—The requirements of subsection (e) of section 4 for supervised private applicators shall become effective 1 year after the expiration of the period prescribed by subsection (h) of such section within which training programs of such State under subsection (e) are required to be in compliance with minimum standards prescribed by the Administrator of the Environmental Protection Agency under such subsection.

(3) ENFORCEMENT OFFICER TRAINING.—The requirements of subsection (j) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (as added by subsection (a)) shall become effective 1 year after the Administrator issues the training materials specified in subsection (g) of such section.

TITLE V—ADMINISTRATIVE REVIEW

SEC. 501. CANCELLATION AFTER FIVE YEARS.

Section 6(a) (7 U.S.C. 136d(a)) is amended—

(1) by striking out paragraph (2); and

(2) in paragraph (1)—

(A) by striking out "(1) PROCEDURE.—";

(B) by striking out ": *Provided*" and all that follows in the first sentence and inserting in lieu thereof a period; and

(C) by inserting the matter in such paragraph after the subsection heading so that it is flush with the full left-hand margin of the section.

SEC. 502. CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.

Subsection (b) of section 6 (7 U.S.C. 136d(b)) is amended to read as follows:

"(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.—

"(1) NOTICE OF CANCELLATION OR CHANGE IN CLASSIFICATION.—

"(A) If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

"(i) to cancel its registration or to change its classification, together with the reasons (including the factual basis) for the action of the Administrator; or

"(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

"(B) A notice issued under subparagraph (A) shall be sent to each registrant of the pesticide with respect to which the notice is issued and shall be made public.

"(C) In determining whether to issue a notice under subparagraph (A), the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

"(D)(i) Not later than 60 days before sending a notice to a registrant or making public such notice under subparagraph (B), whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of the proposed notice under subparagraph (A) and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture shall provide comments on such notice and analysis to the Administrator within 30 days after receiving the copy of such notice.

"(ii)(I) If the Secretary of Agriculture provides such comments in writing within 30 days after receiving the copy of such notice, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

"(II) If the Secretary of Agriculture does not provide such comments in writing within 30 days after receiving the copy of such notice, the Administrator may notify the registrant and make public the notice at any time after such 30-day period.

"(iii) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary of Agriculture.

"(E) If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirements of notice to the Secretary of Agriculture prescribed by subparagraph (D) and submission to the Scientific Advisory Panel under section 25(d) and proceed in accordance with subsection (c).

"(2) HEARING.—

"(A) The action proposed in a notice issued under paragraph (1)(A) shall become final and effective at the end of 30 days after receipt by the registrant or publication of a notice issued under paragraph (1)(B), whichever occurs later, unless within that time—

"(i) the registrant makes the necessary corrections, if possible; or

"(ii) a request for a hearing is made by a person adversely affected by the notice.

"(B) Whenever a request for a hearing is made, the request shall—

"(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed; and

"(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

"(C) Any party to the proceeding may identify findings and conclusions in dispute.

"(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

"(E) On receipt of a request for a hearing from a person without an economic interest in the pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man or the environment.

"(3) FACTORS.—In taking any action under paragraph (1), the Administrator shall—

"(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restriction; and

"(B) consider the impact of such action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.

"(4) LABEL CHANGES.—

"(A)(i) The Administrator may—

"(I) notify the registrant of a pesticide of a label change proposed by the Administrator that may be made by rulemaking under subparagraph (B); and

"(II) provide that the registrant may submit comments to the Administrator on such proposed change during the 30-day period beginning on the date of the receipt of such notice.

"(ii) If a registrant who is notified by the Administrator of a proposed label change notifies the Administrator that the registrant does not object to such change, such change shall take effect as prescribed by the Administrator.

"(iii) If a registrant who is notified by the Administrator of a proposed label change does not submit comments to the Administrator in such 30-day period, the Administrator shall send such registrant a second notice stating that, if such registrant does not submit any comments to the Administrator in the 30-day period beginning on the date the registrant receives the second notice, the registration of such registrant shall be canceled without a hearing or further notice. The registration of a registrant who does not submit comments on a second notice within such 30-day period shall be canceled without a hearing or further notice.

"(iv) If in response to a notice under this subparagraph a registrant submits comments to the Administrator objecting to a proposed label change, the Administrator may proceed under subparagraph (B).

"(B)(i) The Administrator may require changes to the label of a pesticide by informal rulemaking under this paragraph unless the changes—

"(I) are equivalent to a cancellation of a use;

"(II) render the pesticide unmarketable; or

"(III) otherwise have a major economic impact on persons affected by such changes.

"(ii) If the Administrator may not require changes to the label of a pesticide by informal rulemaking under this paragraph because of subclause (I) or (II) of clause (i), the Administrator may only require such changes by a proceeding authorized by other provisions of this Act.

"(C)(i) After the promulgation of a regulation under subparagraph (B), the Administrator shall—

"(I) notify each registrant of the pesticide subject to the regulation of the label change required by the regulation; and

"(II) provide a 30-day period for each registrant to apply to the Administrator for an amendment to the registration to comply with the regulation.

“(C) If a registrant does not apply for such an amendment within such period, the Administrator shall issue a notice of intent to cancel the registration of such registrant in accordance with paragraph (2). For purposes of paragraph (2), such notice shall be deemed to have been issued under paragraph (1).

“(D) A registrant or user of a pesticide subject to a regulation issued under subparagraph (B) may request a hearing under subsection (d) on such regulation in accordance with paragraph (2). The scope of the hearing shall be limited to—

“(i) whether the pesticide complies with the regulation;

“(ii) whether the regulation by its terms is applicable to such pesticide; and

“(iii) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was promulgated, it would be unreasonable to require such pesticide to comply with the regulation.

"(E)(i) Except as provided in clause (ii), in an action under section 16(e) for review of a regulation issued under subparagraph (B), the court, on request, shall postpone the effective date of the regulation until completion of the review action if the petitioner shows—

"(I) a likelihood of success on the merits in such action; and

"(II) that the implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner.

"(ii) A court in a review action under section 16(e) shall not postpone the effective date of a regulation issued under subparagraph (B) if the Administrator shows that failure to implement the regulation before completion of the action would cause a risk of substantial harm to health or the environment.".

SEC. 503. PUBLIC HEARINGS AND SCIENTIFIC REVIEW.

Section 6(d) (7 U.S.C. 136d(d)) is amended—

(1) by striking out the fifth through ninth sentences;

(2) in the tenth sentence—

(A) by striking out "(including the report of the Academy)"; and

(B) by striking out "90 days thereafter" and inserting in lieu thereof "18 months after issuance of the notice that gave rise to the hearing";

(3) by inserting before the last sentence the following new sentence: "The time period prescribed by the preceding sentence may be extended by the Administrator under extraordinary circumstances for not more than 1 year."; and

(4) in the heading, by striking out "AND SCIENTIFIC REVIEW".

SEC. 504. CONDITIONAL REGISTRATION.

Section 6(e)(1) (7 U.S.C. 136d(e)(1)) is amended by striking out ": *Provided*" and all that follows and inserting in lieu thereof a period.

SEC. 505. HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.

Section 6 (7 U.S.C. 136d) is amended—

(1) by redesignating subsection (f) as subsection (j); and

(2) by inserting after subsection (e) the following new subsection:

"(f) HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

"(1) GENERAL RULE.—Except as provided in paragraphs (2) and (3), subsection (d) shall govern any hearing under such subsection—

"(A) that results from the final determination of the Administrator in a public interim administrative review proceeding under section 3(c)(8) that is initiated after January 1, 1988;

"(B) that includes an opportunity for comment on a notice of preliminary determination issued in connection with such review; and

"(C) for which the time between the first public notice for such review under section 3(c)(8)(F) and the close of the last comment period provided for such review is not less than 180 days.

"(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in such pesticide) following a public interim administrative review described by paragraph (1) may request, or intervene in, a hearing in the manner provided by subsection (b)(2)(B) within 30 days after such decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with section 3(c)(8)(F).

"(3) PROCEDURES.—

"(A) At the request of a party, an administrative law judge conducting a hearing may receive into evidence portions of a public interim administrative review record and other evidence, if the party demonstrates that such portions of the record and other evidence are relevant and material to the disputed issues and are not unduly repetitious, and if a competent witness is made available to be cross-examined on all matters relating to such evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the public interim administrative review proceeding by the exercise of due diligence by the offering party shall not be admissible.

"(B) The right of other parties to confront and cross-examine witnesses with respect to such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross-examination is not unduly repetitious.

"(C)(i) Not later than 120 days after an administrative law judge is appointed, prehearing matters shall be completed and the hearing shall commence.

"(ii) The administrative law judge may establish a schedule for prehearing matters, including discovery and motions, and shall ensure that the hearing schedule is met. The administrative law judge shall issue such orders as are appropriate for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision.

"(iii) Discovery shall be permitted after the expiration of 120 days after the appointment of the administrative law judge on a determination by the administrative law judge that—

"(I) such discovery shall not in any way unreasonably delay the proceeding;

"(II) the information to be obtained is not otherwise obtainable; and

"(III) such information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

"(D) Any challenge to—

"(i) the authority to issue; or

"(ii) the procedural correctness of the issuance of,

any notice of intent to cancel or change classification or to any request for a hearing or motion to intervene shall be filed with the administrative law judge not later than 30 days before the commencement of the evidentiary phase of the hearing.

"(E) Not later than 30 days before the hearing commences, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits that the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended on motion by a party.

"(F) If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and when in the judgment of the administrative law judge it is necessary, may submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis under such time limits as may be established by the administrative law judge.

"(G) The administrative law judge shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that the schedule shall not prejudice the right of a party to present evidence. The person who requested a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

"(H) A hearing conducted in accordance with this subsection shall be completed and the Administrator shall make a final decision within 300 days after the issuance of the notice that gave rise to the hearing. The time limit imposed by this subparagraph may not be extended, except in exceptional circumstances in which such extension is essential for a fair and accurate determination of pivotal facts central to the proceeding. In no event may such time limit be extended more than 180 days. Any other time limit imposed by this paragraph may be extended for good cause.

"(I) Failure to complete a hearing and make a final decision within the time period prescribed by subparagraph (H) shall be grounds for a civil action in a district court of the United States seeking an order to establish a schedule requiring the prompt completion of the hearing, but shall not be grounds for termination of the hearing or for making a final decision respecting the pesticide that is the subject of the hearing.".

SEC. 506. ADMINISTRATIVE REVIEW.

Section 6 (7 U.S.C. 136d) (as amended by section 505 of this Act) is further amended by inserting after subsection (f) the following new subsection:

"(g) GENERAL PROVISIONS.—

"(1) VOLUNTARY CANCELLATION.—A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request.

"(2) PUBLICATION OF NOTICE.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 3A, or a notice issued under the third sentence of subsection (b)(4)(A), shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

"(3) EXISTING STOCKS.—The Administrator may permit the continued use, distribution, or sale, or any combination thereof, of existing stocks of a pesticide whose registration is canceled under this Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

"(4) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator. For purposes of this paragraph, the term 'information' includes factual information and expert opinion regarding risks or benefits.".

SEC. 507. CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.

Section 6 (7 U.S.C. 136d) (as amended by section 506 of this Act) is further amended by inserting after subsection (g) the following new subsection:

"(h) SUSPENSION AND CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

"(1) NOTICE.—

"(A) The Administrator shall immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if—

"(i) before the effective date of this subsection, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by the registrant of the pesticide to the Administrator in support of such registration were invalid;

"(ii) the data referred to in clause (i)—

"(I) have not been replaced as of the effective date of such Act; or

"(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988; and

"(iii) such data are material to the registration.

"(B) The Administrator may issue an order of suspension and a notice of intent to cancel the registration of a pesticide by a registrant who cited data described in subparagraph (A) in support of the registration of the pesticide.

"(2) INVALID DATA.—

"(A) If, after the effective date of this subsection, the Administrator determines that invalid data are submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

"(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

"(ii) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

"(B) If, after the effective date of such Act, the Administrator determines that invalid data are cited by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

"(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

"(ii) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

"(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue notices of intent to suspend and cancel such registration.

"(4) HEARING.—

"(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on the date of receipt by the registrant of a notice issued under this subsection unless during such period a request for a hearing is made by a person adversely affected.

"(B) A hearing under this paragraph shall be conducted in accordance with the procedures prescribed by subsection (c) or (d), as appropriate.

"(C) In the case of a hearing held with respect to action proposed to be taken under paragraph (1), the only matters for resolution shall be whether—

"(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

"(I) have not been replaced as of the effective date of this subsection; or

"(II) are in the process of being replaced on the effective date of such Act but are not submitted to the Administrator by April 1, 1988; and

"(ii) the data are material to the registration.

"(D) In the case of a hearing held with respect to action proposed to be taken under paragraph (2), the only matters for resolution shall be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

"(E) In the case of a hearing held with respect to action proposed to be taken under paragraph (3), the only matters for resolution shall be whether a registrant willfully submitted material data known to be false.

"(F) A decision after completion of a hearing conducted under this paragraph shall be final.

"(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.".

SEC. 508. NOTICE FOR STORED PESTICIDES WITH CANCELED OR SUSPENDED REGISTRATIONS.

Section 6 (7 U.S.C. 136d) (as amended by section 507 of this Act) is amended by adding at the end the following:

"(i) NOTICE FOR STORED PESTICIDES WITH CANCELED OR SUSPENDED REGISTRATIONS.—

"(1) IN GENERAL.—Any producer or exporter of a pesticide, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, pesticide testing facility, commercial applicator, or any person who distributes or sells any pesticide that has in its possession any pesticide that has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

"(A) such possession;

"(B) the quantity of such pesticide in its possession; and

"(C) the place at which such pesticide is stored.

"(2) COPIES.—The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency that has jurisdiction over the place of pesticide storage identified in the notice.".

TITLE VI—REGISTRATION OF ESTABLISHMENTS

SEC. 601. CONFIDENTIAL INFORMATION.

Section 7(d) (7 U.S.C. 136e(d)) is amended by inserting "and production locations" after "names".

SEC. 602. FACT SHEETS AND REPORTS.

Section 7 (7 U.S.C. 136e) is amended by adding at the end thereof the following new subsection:

"(e) PUBLIC RIGHT TO KNOW.—

"(1) FACT SHEETS.—Any producer operating an establishment in any State shall prepare or obtain a fact sheet complying with this subsection for each active ingredient manufactured or used at the establishment. The producer shall maintain copies of the fact sheet at the establishment and shall furnish a copy to any person on request.

"(2) CONTENTS.—

"(A) Each fact sheet for an ingredient required under paragraph (1) shall—

"(i) contain the chemical name, each common name, and any trade name of the ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient; and "(ii) be revised as often as is necessary to reflect current information about the ingredient.

"(B) The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

"(3) REPORTS.—Each producer to whom this subsection applies shall furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes—

"(A) for each establishment operated by the producer in any State, the name of each ingredient for which a fact sheet is required that is manufactured or used at that establishment;

"(B) for each ingredient for which a fact sheet is required, the location of each establishment where such ingredient is manufactured or used by the producer; and

"(C) a current copy of each required fact sheet.

"(4) PUBLIC AVAILABILITY.—The fact sheets required by paragraph (1) and the annual reports required by paragraph (3) shall be available to the public.".

SEC. 603. INFORMATION REQUESTED.

Section 7 (7 U.S.C. 136e) (as amended by section 602 of this Act) is further amended by adding at the end thereof the following new subsection:

"(f) INFORMATION REQUESTS.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall catalog and retrieve data in such a manner as to eliminate or reduce burdensome requests to registrants for submission of information, particularly requests that require the submission of duplicate confidential data.".

TITLE VII—BOOKS AND RECORDS

SEC. 701. RECORDS.

Section 8 (7 U.S.C. 136f) is amended to read as follows:

"SEC. 8. RECORDS.

"(a) AUTHORITY TO REQUIRE RECORDS.—

"(1) IN GENERAL.—The Administrator, by regulation, may require any producer or exporter of a pesticide, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, commercial applicator, or any person who distributes or sells a pesticide—

"(A) to prepare, and to maintain for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act;

"(B) to furnish to the Administrator reports stating the location where the records are maintained; and

"(C) to furnish a copy of any such record to the Administrator on written request.

"(2) Retail distribution or sale.—Except as provided in subsections (c), (d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain, or furnish any record under this subsection with respect to such pesticide.

"(b) Limitations.—The Administrator may not, under the authority of subsection (a), require any person to maintain records of—

"(1) financial data, sales data, or pricing data;

"(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure; or

"(3) research or test data other than—

"(A) data relating to a registered pesticide;

"(B) data relating to any pesticide for which an application for registration or for an experimental use permit has been filed; or

"(C) data relating to testing at a pesticide testing facility.".

SEC. 702. RECORDS OF PESTICIDE APPLICATORS AND DEALERS.

Section 8 (7 U.S.C. 136f) (as amended by section 701 of this Act) is further amended by adding at the end thereof the following new subsections:

"(c) RECORDS OF APPLICATORS.—

"(1) COMMERCIAL APPLICATORS.—The Administrator shall require each commercial applicator to maintain records of each pesticide application, including the identity and quantity of pesticide applied and the date and location of such application, for a period of 2 years after each such application.

"(2) PRIVATE APPLICATORS.—No regulations issued by the Administrator to carry out this Act may require any private applicator to maintain any records or file any reports or other documents.

"(d) RECORDS OF PESTICIDE DEALERS.—

"(1) IN GENERAL.—The Administrator, by regulation, shall require each pesticide dealer to maintain a record of each sale or distribution of—

"(A) a pesticide classified for restricted use; and

"(B) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

"(2) CONTENTS.—Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold.

"(3) DURATION.—A pesticide dealer shall maintain the records required under this subsection for 3 years after the date of the distribution or sale.

"(e) ACCESS.—

"(1) EMPLOYEES, CUSTOMERS, AND COMPLAINANTS.—

"(A) A pesticide dealer or commercial applicator shall afford to an employee or former employee of such dealer or applicator access to records required to be kept under subsections (c) and (d) that directly relate to the employment duties of the employee.

"(B) A pesticide dealer or commercial applicator shall afford to a customer of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by such an applicator at the request of the customer or under a contract with a customer.

"(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

"(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph, except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours, after the request is made.

"(2) STATE AGENCIES.—A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 on request by such State agency to the commercial applicator or dealer required to maintain such records.

"(f) INFORMATION FOR EMPLOYEES.—An employer who uses or supervises the use of a pesticide shall—

"(1) know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and to the safety, first aid, and antidote information listed on the labeling of the pesticide; and

"(2) be responsible for promptly making such information available, on request, to any employee exposed to the pesticide and to treating medical personnel.".

TITLE VIII—INSPECTION OF ESTABLISHMENTS

SEC. 801. AUTHORITY TO ENTER, INSPECT, AND COPY.

Subsection (a) of section 9 (7 U.S.C. 136g(a)) is amended to read as follows:

"(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—An officer or employee of the United States or of any State, duly designated by the Administrator, is authorized at reasonable times, as provided by this section—

"(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

"(2) in the case of a pesticide the registration of which has been canceled or suspended under section 6 and that the Administrator has reasonable cause to believe may pose a danger to public health or safety, to enter any place where the pesticide is stored to inspect and obtain samples of any pesticide, active ingredient, or device being stored at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

"(3) to enter any place where there are located any records required under this Act or any place reported under section 8(a) as a location where such records are maintained, to inspect and obtain copies of such records;

"(4) to enter any pesticide testing facility—

"(A) to inspect the facility and the testing being conducted at the facility; and

"(B) to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

"(5) to enter any place where such officer or employee has reason to believe that this Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, to inspect such place to obtain evidence of such violation.".

SEC. 802. WARRANTS.

Subsection (b) of section 9 (7 U.S.C. 136g(b)) is amended to read as follows:

"(b) WARRANTS.—An officer or employee of the United States or of any State, duly designated by the Administrator, is empowered to obtain and execute warrants authorizing—

"(1) entry, inspection, and obtaining of evidence for the purposes of this section;

"(2) inspection and copying of all records required under this Act; and

"(3) seizure of any pesticide or device that is in violation of this Act.".

SEC. 803. PROCEDURE, COORDINATION, AND CRIMINAL VIOLATIONS.

Section 9 (7 U.S.C. 136g) is amended by adding at the end thereof the following new subsections:

"(d) Procedure.—

"(1) Credentials and statements.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the entry or inspection and whether a violation of this Act is suspected.

"(2) Promptness.—Each entry or inspection shall be commenced and completed with reasonable promptness.

"(3) Samples.—If the person conducting the entry or inspection obtains a sample of a pesticide or device, before leaving the premises such person shall give to the person in charge of the premises a receipt describing the sample and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished on request to the person in charge of the premises.

"(e) Coordination.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication of inspections.

"(f) CRIMINAL VIOLATIONS.—An officer or employee of the United States or of any State, duly designated by the Attorney General, may obtain and execute a warrant in accordance with rule 41 of the Federal Rules of Criminal Procedure if a court or magistrate determines under such rule that there is probable cause to believe that—

"(1) a criminal violation of this Act has occurred or is occurring on the property to be entered or searched; or

"(2) evidence of a criminal violation of this Act will be found on such property.".

TITLE IX—PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

SEC. 901. DISCLOSURE OF INERT INGREDIENTS.

The first sentence of section 10(d)(3) (7 U.S.C. 136h(d)(3)) is amended by striking out "If" and inserting in lieu thereof "Except with respect to disclosure of information on inert ingredients in ingredient statements in accordance with section 2(n), if".

SEC. 902. DATA DISCLOSURE TO STATES.

Section 10 (7 U.S.C. 136h) is amended by adding at the end thereof the following new subsection:

"(h) DATA DISCLOSURE TO STATES.—

"(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

"(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

"(A) the disclosure or use of data or information provided by the Administrator under paragraph (1) to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property; and

"(B) the act of a State with respect to such data or information shall be considered an act of the United States.

"(3) REQUIRED DISCLOSURE.—The Administrator shall disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that—

"(A) the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section; and

"(B) the law of the State allows the submitter of the data or information to recover just compensation in a civil action against the State for losses resulting from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or this section.".

TITLE X—STANDARDS APPLICABLE TO PESTICIDE APPLICATORS

SEC. 1001. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

Section 11 (7 U.S.C. 136i) is repealed.

TITLE XI—UNLAWFUL ACTS

SEC. 1101. UNLAWFUL ACTS.

(a) In General.—Section 12(a) (7 U.S.C. 136j(a)) is amended—

(1) in paragraph (1)—

(A) by striking out "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—" and inserting in lieu thereof "distribute or sell to any person—"; and

(B) by striking out subparagraph (A) and inserting in lieu thereof the following new subparagraph:

"(A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;"; and

(2) in paragraph (2)—

(A) by striking out subparagraph (B) and inserting in lieu thereof the following new subparagraph:

"(B) to refuse to—

"(i) prepare, maintain, or submit any records required by or under this Act;

"(ii) submit any reports required by or under this Act; or

"(iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;";

(B) in subparagraph (F), by striking out "to make" and inserting in lieu thereof "to distribute or sell, or to make";

(C) by striking out subparagraphs (J) and (K) and inserting in lieu thereof the following new subparagraphs:

"(J) to violate any suspension order issued under section 3(c)(2)(B), 3A, or 6;";

"(K) to violate any cancellation order issued under this Act or to fail to submit a notice in accordance with section 6(i);";

(D) in subparagraph (M), by striking out "section 8" and inserting in lieu thereof "this Act";

(E) by striking out "or" at the end of subparagraph (O);

(F) by striking out the period at the end of subparagraph (P) and inserting in lieu thereof a semicolon; and

(G) by adding at the end thereof the following new subparagraphs:

"(Q) to obtain or use records acquired under section 8(e) in furtherance of a commercial purpose;

"(R) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

"(S) to submit to the Administrator data known to be false in support of a registration; or

"(T) to violate any regulation issued under section 3(a), 19(a), 25(c)(3), or 25(f).".

(b) ACTS OF OFFICERS, AGENTS, ETC.—Section 12 (7 U.S.C. 136j) is amended by adding at the end thereof the following new subsection:

"(c) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall be deemed to be the act, omission, or failure of such person as well as that of the person employed.".

TITLE XII—PENALTIES

SEC. 1201. PENALTIES AND SUBPOENAS.

(a) CIVIL PENALTIES.—Section 14(a) (7 U.S.C. 1361(a)) is amended—

(1) by striking out paragraphs (1) and (2) and inserting in lieu thereof the following new paragraphs:

"(1) IN GENERAL.—

"(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If such a person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $50,000 for such subsequent violation.

"(B) Any—

"(i) commercial applicator of restricted use pesticides; or

"(ii) any other person not described in subparagraph (A) who distributes or sells pesticides or devices,

that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $20,000 for such subsequent violation.

"(2) PRIVATE APPLICATOR.—Any private applicator who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, and any other person not included in paragraph (1) that violates any provision of this Act, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $2,000 for such subsequent violation. The Administrator may waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused significant harm to health or the environment.";

(2) in paragraph (3), by adding at the end thereof the following new sentence: "If the person neither resides nor has a principal place of business in the United States, the Administrator may designate a site

for the hearing in the United States that is reasonably convenient for the parties."; and

(3) in the first sentence of paragraph (4), by inserting "the economic benefit (if any) resulting from the violation," after "to continue in business,".

(b) SUBPOENAS.—Section 14(a) is amended by adding at the end thereof the following new paragraph:

"(6) SUBPOENAS.—The Administrator, in connection with administrative proceedings under this subsection, may issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and may request the Attorney General to bring an action to enforce any subpoena issued under this paragraph. The district courts of the United States shall have jurisdiction to enforce such subpoenas and impose sanctions.".

(c) CRIMINAL PENALTIES.—Section 14(b) is amended—

(1) by striking out paragraph (1) and inserting in lieu thereof the following new paragraph:

"(1) IN GENERAL.—

"(A) Any registrant, applicant for a registration, producer, or pesticide testing facility that knowingly violates any provision of this Act shall be fined not more than $50,000 or imprisoned for not more than 1 year, or both.

"(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, that knowingly violates any provision of this Act shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both."; and

(2) in paragraph (2)—

(A) by striking out "$1,000" and inserting in lieu thereof "$2,000"; and

(B) by striking out "30" and inserting in lieu thereof "60".

(d) DISCLOSURE OF INFORMATION.—Paragraph (3) of section 14(b) is amended to read as follows:

"(3) DISCLOSURE OF INFORMATION.—

"(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 shall be fined not more than $25,000 or imprisoned for not more than 3 years, or both.

"(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

"(i) is granted access to data under section 3(c)(9); and

"(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

"(I) knowingly violates such section; or

"(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000 or imprisoned for not more than 3 years, or both.".

(e) DETERMINATION OF PENALTY.—Paragraph (4) of section 14(b) is repealed.

TITLE XIII—INDEMNITIES

SEC. 1301. INDEMNIFICATION BY EPA.

Section 15 (7 U.S.C. 136m) is amended by adding at the end thereof the following subsection:

"(c) INDEMNIFICATION.

"(1) REPORT.—If the Administrator takes an action under subsection (a) that requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on—

"(A) the action taken that requires the payment of indemnification;

"(B) the reasons for taking such action;

"(C) the estimated cost of the payment; and

"(D) a request for the appropriation of funds for such payment.

"(2) ADVANCE APPROPRIATION REQUIRED.—The Administrator may not make such payment unless a specific line item appropriation of funds has been made in advance for such payment.".

TITLE XIV—ADMINISTRATIVE PROCEDURE

SEC. 1401. REVIEW OF REGULATIONS.

Section 16 (7 U.S.C. 136n) is amended by adding at the end thereof the following new subsection:

"(e) REVIEW OF REGULATIONS.—

"(1) IN GENERAL.—

"(A) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of this subsection shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the regulation by filing a petition for review in the

United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any petition under this paragraph for review of a regulation shall be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register.

"(B) Any refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a refusal to modify or rescind a regulation shall be filed within 120 days after such refusal.

"(C) The scope of review under subparagraph (A) or (B) shall be as specified in section 706 of title 5, United States Code. The commencement of a proceeding under subparagraph

(A) or (B), unless specifically ordered by the court to the contrary, shall not operate as a stay of the regulation.

"(2) JUDICIAL REVIEW.—A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall not be subject to judicial review—

"(A) in any suspension, cancellation, or denial proceeding under this Act or in any appeal therefrom; or

"(B) in any proceeding under section 13 or 14(a), or subsection (c), or in any appeal therefrom except on request of a person who, as an agricultural producer, is adversely affected by such action.

"(3) STAYS.—If a person who is a party to a proceeding described in subparagraph (A) or (B) of paragraph (2) that is based on a regulation issued under this Act petitions the Administrator to modify or rescind such regulation, the application of such regulation in the proceeding shall be stayed until the Administrator issues a final decision on the petition.

"(4) DEFINITION OF AGRICULTURAL PRODUCER.—As used in this subsection, the term 'agricultural producer' means a nongovernmental producer of an agricultural commodity who—

"(A) uses or supervises the use of any pesticide for the production of such commodity on property owned or rented by the producer or the employer of the producer; or

"(B) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the land of the producer.".

TITLE XV—IMPORTS AND EXPORTS

SEC. 1501. PESTICIDES AND DEVICES INTENDED FOR EXPORT.

(a) IN GENERAL.—Subsection (a) of section 17 (7 U.S.C. 136o(a)) is amended to read as follows:

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

"(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device, or active ingredient used in producing a pesticide, intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to section 2(p), subparagraphs (A), (C), (D), (E), (G), (H), and (I) of section 2(q)(1), subparagraphs (A), (B), (C)(i), (C)(iii), and (D) of section 2(q)(2), sections 7 and 8, and paragraphs (2), (3), and (4) of this subsection.

"(2) EXPORT OF RESTRICTED USE OR UNREGISTERED PESTICIDES.—

"(A) This paragraph applies to a pesticide, device, or active ingredient—

"(i) for which a restricted use classification has become effective under section 3;

"(ii) for which a cancellation or suspension has become effective under section 6;

"(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal is associated with concern over potential adverse public health or environmental effects; or

"(iv) that is not registered under section 3 for any use.

"(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless, at least 30 days before the first shipment each year of such pesticides, devices, or active ingredients to such country, such person has—

"(i) notified, under paragraph (3), the person importing the pesticide, device, or active ingredient and the appropriate government regulatory office in the importing country;

"(ii) received written evidence that the notification was delivered to the appropriate government regulatory office; and

"(iii) submitted a copy of the notification (in English) and evidence of delivery to the Administrator.

"(C) Documents referred to in subparagraph (B) shall be made available to the public, on request.

"(3) NOTIFICATION SPECIFICATIONS.—The notification required under paragraph (2) shall be made in an appropriate language and shall contain—

"(A) the name of the pesticide and the common and chemical names of each active ingredient;

"(B) the name and address of the person exporting the pesticide, device, or active ingredient;

"(C) the name and address of the person importing the pesticide, device, or active ingredient;

"(D) the name and address of the appropriate government regulatory office in the importing country;

"(E) a statement of the reasons why the registration of the pesticide was canceled, suspended, voluntarily withdrawn, or the pesticide, is not registered in the United States, or is classified for restricted use, and the list of restrictions; and

"(F) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

"(4) LABELS.—

"(A) The label of a pesticide intended for export from the United States shall be written in an appropriate language.

"(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.

"(5) Records.—The Administrator, by regulation, may require any person subject to this subsection to prepare, maintain, and submit such records as may be necessary to carry out this subsection.".

(b) Effective Dates and Implementation.—

(1) In general.—Paragraphs (2) and (3) of section 17(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (as amended by subsection (a) of this section) shall become effective 90 days after the effective date of this Act.

(2) Publication of list.—Not later than 30 days after the effective date of this Act, the Administrator of the Environmental Protection Agency shall publish in the Federal Register a list of the names, addresses, and international telecommunications codes of appropriate regulatory offices required to receive notices under section 17(a)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (as amended by subsection (a)).

(3) Revision of list.—Not later than 180 days after the effective date of this Act, and annually thereafter, the Administrator shall revise the list required under paragraph (2).

(4) Preliminary guidelines.—Not later than 90 days after the effective date of this Act, the Admin-

istrator shall publish in the Federal Register preliminary guidelines regarding—

(A) the form of the notification required under section 17(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (as amended by subsection (a));

(B) translation of the notification and labels required under such section 17(a) into the appropriate language;

(C) preparation and retention of records under such section 17(a); and

(D) procedures for public access to documents submitted by exporters under such section.

SEC. 1502. CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.

Subsection (b) of section 17 (7 U.S.C. 136o(b)) is amended to read as follows:

"(b) NOTICES OF REGULATORY ACTION FURNISHED TO FOREIGN GOVERNMENTS.—

"(1) ISSUANCE.—The Administrator shall promptly transmit through the Secretary of State a notice, at such time and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever—

"(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective; or

"(B) a pesticide is classified for restricted use.

"(2) CONTENTS.—A notice under paragraph (1) shall include—

"(A) the reasons for the regulatory action taken;

"(B) in the case of a canceled or suspended registration of a pesticide, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide; and

"(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.".

SEC. 1503. COOPERATION IN INTERNATIONAL EFFORTS.

Subsection (d) of section 17 (7 U.S.C. 136o(d)) is amended to read as follows:

"(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

"(1) in cooperation with the Secretary of State, other appropriate Federal agencies, and nongovernmental and international organizations, actively participate in international efforts to develop improved pesticide research and regulatory programs,

"(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs,

"(3) within 1 year after the effective date of this subsection, and every 3 years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to ascertain what procedures are in place in each country—

"(A) regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides;

"(B) to control residues on foods to meet tolerances established under United States law; and

"(4) report to Congress annually on the activities conducted under this subsection and the results thereof.".

TITLE XVI—DISPOSAL AND TRANSPORTATION

SEC. 1601. PESTICIDE CONTAINERS.

Section 19 (7 U.S.C. 136q) is amended by adding at the end thereof the following new subsections:

"(d) CONTAINER DESIGN.—

"(1) PROCEDURES.—

"(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.

"(B) The regulations shall assure, to the fullest extent practicable, that the containers—

"(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

"(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers;

"(iii) facilitate the safe disposal of the containers; and

"(iv) facilitate the safe refill and reuse of the containers.

"(2) COMPLIANCE.—The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of this subsection.

"(e) PESTICIDE RESIDUE REMOVAL.—

"(1) PROCEDURES.—

"(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.

"(B) The regulations may—

"(i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;

"(ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;

"(iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and

"(iv) be coordinated with requirements for the rinsing of containers imposed under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.).

"(C) Nothing in this subsection shall affect the authorities or requirements concerning pesticide containers under the Resource Conservation and Recovery Act of 1976.

"(D) The Administrator may, at the discretion of the Administrator, exempt products intended solely for household use from the requirements of this subsection.

"(2) COMPLIANCE.—Effective beginning 5 years after the effective date of this subsection, a State may not exercise primary enforcement responsibility under section 26, or certify an applicator under section 4, unless the Administrator determines that the State is carrying out an adequate program to assure compliance with this subsection.

"(f) PESTICIDE CONTAINER STUDY.—

"(1) STUDY.—

"(A) The Administrator shall conduct a study of options to encourage or require—

"(i) the return, refill, and reuse of pesticide containers;

"(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

"(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

"(B) In conducting the study, the Administrator shall—

"(i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and

"(ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

"(2) Report.—Not later than 2 years after the effective date of this subsection, the Administrator shall submit to Congress a report describing the results of the study required under paragraph (1).".

TITLE XVII—DELEGATION AND COOPERATION

SEC. 1701. DELEGATION AND COOPERATION.

Section 22 (7 U.S.C. 136t) is amended by adding at the end thereof the following new subsection:

"(c) Effect on Certain Other Laws.—

"(1) In general.—In exercising any authority under this Act, the Administrator shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be considered to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that such exercise of authority by the Administrator under this Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970.

"(2) COORDINATION.—To ensure the safety and health of workers, the Administrator and the Secretary of Labor shall seek to reach such agreements and to coordinate the exercise of their statutory authority.".

TITLE XVIII—STATE COOPERATION, AID, AND TRAINING

SEC. 1801. COOPERATIVE AGREEMENTS.

Subsection (a) of section 23 (7 U.S.C. 136u(a)) is amended to read as follows:

"(a) COOPERATIVE AGREEMENTS.—

"(1) PURPOSES.—The Administrator may enter into cooperative agreements with States and Indian Tribes for the following:

"(A) To delegate to any State or Indian Tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian Tribe to cooperate in the enforcement of this Act, and to assist States and Indian Tribes in implementing cooperative enforcement programs through grants.

"(B) To provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as agreed under such cooperative agreements, of conducting training programs for certification of applicators. Funds shall be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator.

"(C) To provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under such cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State plan of each State approved under section 4(a)(2). Funds shall be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

"(2) AUTHORIZATION FOR APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under this subsection.".

TITLE XIX—AUTHORITY OF STATES

SEC. 1901. STATE REGULATION, HOUSEHOLD ANTIMICROBIAL PESTICIDES.

Subsection (a) of section 24 (7 U.S.C. 136v(a)) is amended to read as follows:—

"(a) STATE REGULATION.—

"(1) IN GENERAL.—A State may regulate the sale or use of any Federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

"(2) HOUSEHOLD ANTIMICROBIAL PESTICIDES.—

"(A) This paragraph shall apply to any household antimicrobial pesticide if—

"(i) the pesticide is a formulated end-use product that, as registered, is not intended for use on food or feed;

"(ii) the pesticide has been registered under section 3(c)(5), or reregistered under section 3A, after the effective date of this subsection;

"(iii) the Administrator has determined that the product as so registered or reregistered poses no significant toxicological concern when used in accordance with its labeling;

"(iv) the Administrator has published the determination of no significant toxicological concern in the Federal Register;

"(v) the registrant of the product has offered, at the time the registrant provides the final product label to the Administrator, to provide under the conditions of this Act to the appropriate State authority any data submitted by the registrant to the Administrator in support of the registration; and

"(vi) at least 45 days have elapsed from the date upon which an application for State registration has been filed.

"(B) A State may not prohibit any sale or use permitted under this Act of a pesticide described in subparagraph (A) for which an application for State registration has been filed unless and until the State has finally acted on such application pursuant to applicable State law.

"(C) This paragraph shall cease to be effective 5 years after the date of the enactment of this subsection and shall not be construed during the 5 year effective period to—

"(i) preclude a State from requiring in the State registration process submission of additional data beyond that required by the Administrator; or

"(ii) otherwise affect State authority to regulate the sale or use of a pesticide when final action is taken under State law.

SEC. 1902. STATE REGISTRATIONS.

Section 24(c) (7 U.S.C. 136v(c)) is amended—

(1) in paragraph (1), by adding at the end thereof the following new sentence: "Such registration shall expire and be of no further effect, without further action by the Administrator—

"(A) at the end of the period, if any, provided as the duration of the registration by the State that approved it; or

"(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect."; and

(2) in paragraph (2), by adding at the end thereof the following new sentence: "The Administrator shall

establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use.".

SEC. 1903. DIFFERENCES IN USAGE AND RISK.

Section 24 (7 U.S.C. 136v) is amended by adding at the end thereof the following new subsection:

"(d) DIFFERENCES IN USAGE AND RISK.—In promulgating any regulations or policies pertaining to the sale or use of pesticides within a State, the State may take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.".

TITLE XX—AUTHORITY OF ADMINISTRATOR

SEC. 2001. CONGRESSIONAL REVIEW.

Paragraph (4) of section 25(a) (7 U.S.C. 136w(a)(4)) is amended to read as follows:

"(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.".

SEC. 2002. SCIENTIFIC ADVISORY PANEL.

Section 25(d) (7 U.S.C. 136w(d)) is amended—

(1) in the first sentence, by striking out "The" and inserting in lieu thereof "Except with respect to a referral under section 3(c)(8)(F), the";

(2) by striking out "consist of 7 members" and inserting in lieu thereof "be permanent and consist of 9 members"; and

(3) by striking out the sentence beginning "The advisory panel established".

SEC. 2003. WORKER HEALTH AND SAFETY.

Section 25 (7 U.S.C. 136w) is amended by adding at the end thereof the following new subsection:

"(f) WORKER HEALTH AND SAFETY.—

"(1) IN GENERAL.—

"(A) The Administrator, as soon as practicable after the effective date of this subsection, shall promulgate regulations that require the protection, as appropriate and necessary, of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas.

"(B) The Administrator shall promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement that may be established by the Administrator under this subparagraph shall not apply to any person who is required to receive the training described in subsection (d) or (e) of section 4.

"(C) For purposes of subparagraphs (A) and (B), the term 'employees' does not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

"(2) RULEMAKING PROCEDURES.—

"(A) The Administrator shall promulgate regulations under paragraph (1) for employees not described in subparagraph (B) not later than 3 years after the effective date of this subsection.

"(B) The Administrator shall provide a period of at least 6 months for comments on proposed regulations issued under paragraph (1) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas. Such regulations shall be promulgated not later than 2 years after the effective date of this subsection.

"(3) REPORT ON REGULATIONS.—Not later than 6 months after the date of the publication of the notice of proposed rulemaking issued for the regulations for employees described in paragraph (2)(B) to be promulgated under paragraph (1), the Secretary of Agriculture shall submit to the Administrator a report on the impact, cost, and effectiveness of such regulations on the agricultural community. The Secretary shall submit a copy of such report to Congress.

"(4) COPY OF REGULATIONS.—Simultaneously with the promulgation of regulations under paragraph (1), the Administrator shall transmit a copy of such regulations to the Secretary of the Senate and the Clerk of the House of Representatives. Such regulations may not become effective until the expiration of 120 days after the date such regulations are so transmitted.".

TITLE XXI—STATE PRIMARY ENFORCEMENT RESPONSIBILITY

SEC. 2101. RECORDS.

The second sentence of section 26(c) (7 U.S.C. 136w-1(c)) is amended—

(1) by striking out "Notwithstanding the provisions of section 2(e)(1) of this Act" and inserting in lieu thereof "Notwithstanding section 2(kk)";

(2) by striking out "8(b) of this Act" and inserting in lieu thereof "9"; and

(3) by striking out "9(a) of this Act" and inserting in lieu thereof "9".

SEC. 2102. EXPIRATION OF STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

Section 26 (7 U.S.C. 136w–1) is amended by adding at the end thereof the following new subsection:

"(d) EXPIRATION.—Notwithstanding subsections (a) and (b), the primary enforcement responsibility of a State under this section for pesticide use violations shall expire on September 1, 1990, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least equal to those provided in section 14.".

TITLE XXII—FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS

SEC. 2201. AUTHORITY FOR EPA ACTION.

The second sentence of section 27(a) (7 U.S.C. 136w–2(a)) is amended to read as follows: "If a State—

"(1) does not promptly initiate appropriate investigative action after receiving such referral; or

"(2) does not initiate appropriate enforcement action within 90 days after receipt of such referral, the Administrator may act on such complaint or information in accordance with this Act.".

TITLE XXIII—AUTHORIZATION FOR APPROPRIATIONS

SEC. 2301. AUTHORIZATION FOR APPROPRIATIONS.

Effective October 1, 1987, section 31 (7 U.S.C. 136y) is amended to read as follows:

"**SEC. 31. AUTHORIZATION FOR APPROPRIATIONS.**

"There is authorized to be appropriated to carry out this Act (other than section 23(a))—

"(1) $103,363,500 for fiscal year 1988, of which not more than $13,735,500 shall be available for research under this Act;

"(2) $112,414,200 for fiscal year 1989, of which not more than $14,343,600 shall be available for research under this Act;

"(3) $116,673,400 for fiscal year 1990, of which not more than $14,978,200 shall be available for research under this Act;

"(4) $123,305,800 for fiscal year 1991, of which not more than $15,625,900 shall be available for research under this Act; and

"(5) $131,808,700 for fiscal year 1992, of which not more than $16,300,100 shall be available for research under this Act.".

TITLE XXIV—OTHER PROVISIONS

SEC. 2401. IR4 PROGRAM.

Section 2(c) of the entitled "An Act to facilitate the work of the Department of Agriculture, and for other purposes", approved August 4, 1965 (7 U.S.C. 450i(c)), is amended by inserting before the first sentence after paragraph (2) the following new sentence: "The Secretary in making grants under paragraph (2)(B) shall provide support for the interregional project number 4 program (commonly referred to as the 'IR4 program').".

SEC. 2402. RESTORATION OF PATENT TERM FOR CERTAIN AGRICULTURAL AND CHEMICAL PRODUCTS.

Chapter 14 of title 35 of the United States Code is amended by adding after section 157 the following:

"§ 158. Restoration of patent term for certain agricultural and chemical products

"(a) The term of a patent that claims a product subject to a regulatory review period, a method for using such a product, or a method for manufacturing such a product shall be extended, in accordance with this section, from the original expiration date of the patent if—

"(1) the owner of record of the patent or its agent notifies the Commissioner in compliance with subsection (d), "(2) the product has been subject to a regulatory review period before its commercial marketing or use,

"(3) the term of the patent has never been extended under this section,

"(4) the term of the patent has not expired before the Commissioner is notified under subsection (d), and

"(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, or

"(B) in the case of a patent that claims a method of manufacturing the product that primarily uses recombinant DNA or hybridoma technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

"(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of any patent that claims a product, be limited to any use approved for the product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred,

"(2) in the case of a patent that claims a method of using a product, be limited to any use claimed by the patent and approved for the product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred,

"(3) in the case of a patent that claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product.

"(c)(1) Subject to paragraph (2), the term of a patent shall be extended by the time equal to the regulatory review period that occurred after such patent was granted, except that—

"(A) the term of any patent may not be extended for more than 5 years,

"(B) no term of any extended patent may exceed 17 years from the date the product for which the patent was issued was first permitted to be commercially marketed or used,

"(C) if the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had not ended, the period of extension for the patent shall not exceed 2 years, and

"(D) if the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had been completed, there shall be no extension of the patent.

"(2) In determining a regulatory review period for purposes of paragraph (1)—

"(A) if an application or notice described in subparagraph (A)(ii), (B), or (C) of paragraph (4) of subsection (g) was rejected because of insufficiency of data or other required information, the period beginning on the date the application or notice was rejected for insufficiency of data and ending on the date the application or notice was subsequently accepted shall be excluded, except that if during such period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted shall not be excluded, and

"(B) the regulatory review period shall be reduced by any period determined under subsection (e) during which the product sponsor did not act with due diligence.

"(3) In no event shall more than one patent be extended for the same regulatory review period for any product.

"(4) In the case of a pesticide, all formulations of such pesticide containing the identical active ingredient shall be considered the same pesticide and no pesticide may be the subject of more than one patent extension.

"(d) To obtain an extension of the term of a patent under subsection (a), the owner of record of the patent or its agent shall notify the Commissioner, within 60 days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. Such notification shall be in writing and shall—

"(1) identify the Federal statute under which regulatory review occurred,

"(2) state the dates on which the regulatory review period commenced and ended and identify the event that caused such period to begin,

"(3) identify the product for which regulatory review was required,

"(4) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(2) occurred have been satisfied and commercial marketing or use of the product is not prohibited under the Federal statute identified under paragraph (1),

"(5) identify the patent and any claim thereof to which the extension is applicable, identify any uses previously authorized, and state that the term of the patent has never been extended under this section and that no other patent has been extended for the regulatory review period for the product, and

"(6) include such patent or other information as the Commissioner may require.

"(e)(1) Within 60 days of the submittal of the extension notification under subsection (d), the Commissioner shall notify—

"(A) the Secretary of Agriculture if the patent claims a plant or plant product or a method of using or manufacturing a plant or plant product, and

"(B) the Administrator of the Environmental Protection Agency if the patent claims a pesticide subject to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), a chemical substance or mixture subject to the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), or a method of using or manufacturing such a pesticide, substance, or mixture,

of the extension notification and shall submit to the Secretary or Administrator who is so notified a copy of the extension notification. Not later than 30 days after the receipt of the extension notification from the Commissioner, the Secretary or Administrator receiving the extension notice shall review the dates contained in such notification and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

"(2)(A) If a petition is submitted to the Secretary or Administrator making the determination under paragraph (1) not later than 180 days after the publication of a determination under paragraph (1) on which it may reasonably be determined that a product sponsor did not act with due diligence during an applicable regulatory review period, the Secretary or Administrator making the determination shall, in accordance with regulations promulgated by the Secretary or Administrator, determine if the product sponsor acted with due diligence during the applicable regulatory review period. The Secretary or Administrator shall make such determination not later than 90 days after the receipt of a petition. The Administrator may not delegate the authority to make such determination to an office below the Assistant Administrator for Pesticides and Toxic Substances.

"(B) The Secretary or Administrator making a determination under subparagraph (A) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination, together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary or Administrator making the determination to hold a hearing on the determination. Such a hearing shall be an informal hearing that is not subject to section 554, 556, or 557 of title 5, United States Code. If such a request is made within such period, the Secretary or Administrator shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary or Administrator who is holding the hearing shall provide notice of the hearing to the product sponsor and to any interested person and provide the product sponsor and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary or Administrator shall affirm or revise the determination that was the subject of the hearing and notify the Commissioner of such affirmation or any revision of the determination and shall publish such affirmation or revision in the Federal Register.

"(C) Failure of a product sponsor to act with due diligence during a regulatory review period shall not be a defense in any action involving the infringement of a patent.

"(D) In a proceeding under this paragraph, the Secretary or Administrator may take into consideration the failure of a product sponsor to submit data that the product sponsor knew or reasonably should have known was necessary to support an application or notice described in paragraph (4) of subsection (g).

"(E) For purposes of this paragraph, the term 'due diligence' means that degree of attention, sustained directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

"(f)(1) The Commissioner shall determine that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with. A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the notification under subsection (d). If the Commissioner determines that the patent is eligible for extension and on receipt of a determination of the applicable regulatory review period under subsection (e), the Commissioner shall issue to the owner of record of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent. The Commissioner shall publish in the Official Gazette of the Patent and Trademark Office a notice of such extension.

"(2) If the term of a patent for which a notification has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under paragraph (1), the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to 1 year if the Commissioner determines that the patent is eligible for extension. Such periods of extension shall not exceed the regulatory review period calculated from the information provided in the notification submitted under subsection (d).

"(g) As used in this section:

"(1) The term 'product' means—

"(A) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act;

"(B) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act; and

"(C) any plant or plant product that (i) is genetically altered, (ii) is defined as a plant pest or potential plant pest under the Federal Plant Pest Act (7 U.S.C. 150aa–150jj), and (iii) is subject to regulation under such Act.

"(2) The term 'major health or environmental effects test' means an experiment or study to determine or evaluate health or environmental effects that requires at least 6 months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

"(3) The term 'product sponsor' means any person who, with the consent of the patent owner, initiates testing or investigations, claims an exemption, or submits an application or notice described in paragraph (4).

"(4) The term 'regulatory review period' has the following meaning:

"(A) With respect to a product that is a pesticide, the term means the sum of—

"(i) the period beginning on the earlier of the date the product sponsor (I) initiates a major health or environmental effects test on such pesticide, or (II) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c), and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 of such Act (7 U.S.C. 136a), and

"(ii) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of such Act and ending on the date such pesticide is first registered, either conditionally or fully, under such section.

"(B) With respect to a product that is a chemical substance for which notice is required under section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) or that is a mixture that contains a substance for which such notice is required and—

"(i) that is subject to a rule requiring testing under section 4(a) of such Act (15 U.S.C. 2603(a)), the term means a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substance or mixture under section 5 of such Act, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside, or

"(ii) that is not subject to a testing rule under section 4 of such Act, the term means a period commencing on the earlier of the date the product sponsor—

"(I) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of such Act, or

"(II) initiates a major health or environmental effects test on such chemical substance or mixture,

and ending on the expiration of the notice period for such substance under section 5 of such Act or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside.

"(C) With respect to a product that is a plant or plant product, the term means the period beginning on the date an application is submitted under section 103 of the Federal Plant Pest Act (7 U.S.C. 150bb) for permission to move the plant or plant product in interstate commerce and ending on the date such application is approved.

"(h) If information submitted by a product sponsor during a regulatory review period is considered a trade secret or confidential commercial or financial information under the law under which such regulatory review occurred, such information may only be disclosed under this section in accordance with such law. This subsection does not prohibit the Commissioner or the Administrator from identifying the patent owner, the product sponsor, the product, the patent, and any other information necessary to identify, describe, and calculate the regulatory review period in any notification, publication, or public record required by this section.

"(i) The Commissioner, the Administrator, and the Secretary of Agriculture may establish such fees as appropriate to cover the costs of carrying out their respective duties and functions under this section.

"(j)(1) Except as provided in paragraph (2), this section shall cease to be in effect on the expiration of 15 years after the date of the enactment of this section.

"(2) This section shall continue to apply to any patent that claims a product subject to a regulatory review period, a method for using such a product, or a method of manufacturing such a product if the patent was issued before the expiration of 15 years after such date.".

(b) CONFORMING AMENDMENT.—The last sentence of section 282 of title 35, United States Code, is amended by inserting "or 158(e)" after "(2)".

(c) ANALYSIS.—The analysis for chapter 14 of title 35 of the United States Code is amended by adding after the item relating to section 157 the following:

"158. Restoration of patent term for certain agricultural and chemical products.".

(d) SECTION 271.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

"(5)(A) Except as provided in subparagraph (B), during the last 2 years of the term of a patent relating to a pesticide (including a patent that claims a pesticide, a method for using a pesticide, or a method of manufacturing a pesticide) that is or has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or that is marketed with the permission of the holder of such patent, it shall not be an act of infringement of such patent to make, use, or sell such pesticide solely for testing reasonably related to the development and submission of data—

"(i) to meet regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act,

"(ii) to obtain a tolerance or an exemption from a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), or

"(iii) to obtain a food additive regulation or an exemption from a food additive regulation under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

"(B)(i) Subparagraph (A) applies only to the first patent issued for a pesticide, a method of using a pesticide, or a method of manufacturing a pesticide that makes the unlicensed manufacture, use, or sale of the pesticide a patent infringement.

"(ii) Subparagraph (A) does not apply to a patent that claims a method of manufacturing a pesticide that uses recombinant DNA or hybridoma technology in the manufacture of the pesticide.

"(C) It shall be an act of infringement for any person to submit any application under the Federal Insecticide, Fungicide, and Rodenticide Act or section 408 or 409 of the Federal Food, Drug, and Cosmetic Act for a pesticide covered by the first composition of matter patent, method of use patent, or method of manufacturing patent issued for the pesticide if such application is submitted before the expiration of the term of such first patent unless such person is the holder of such patent or a licensee of the holder.

"(D) For purposes of this paragraph, all formulations of a pesticide containing the identical active ingredient shall be considered the same pesticide.".

SEC. 2403. TOLERANCES FOR AGRICULTURAL COMMODITIES.

(a) Revocations and Suspensions.—Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) is amended by adding at the end thereof the following new subsection:

"(p)(1)(A) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity—

"(i) has been canceled by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.);

"(ii) has voluntarily been canceled under such Act; or

"(iii) has voluntarily been withdrawn under such Act;

due in whole or in part to dietary risks to humans, the Administrator, not later than 60 days after the effective date of such cancellation or after receipt of information of such withdrawal, shall revoke any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). In revoking a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used.

"(B) The effective date of a revocation under subparagraph (A) may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

"(i) the use of the canceled pesticide before the date of its cancellation;

"(ii) the use of existing stocks of such pesticide as authorized under the order canceling the registration of the pesticide; or

"(iii) unavoidable residual environmental contamination.

"(2) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act due in whole or in part to dietary risks to humans, the Administrator, not later than 60 days after the effective date of such suspension, shall suspend any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). The effective date of such suspension may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

"(A) the use of the suspended pesticide before the date of its suspension;

"(B) the use of existing stocks of such pesticide as authorized under the order suspending the registration of the pesticide; or

"(C) unavoidable residual environmental contamination.

In suspending a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used. The suspension of a tolerance or an exemption from a tolerance for a pesticide chemical shall be effective as long as the registration of the pesticide to which the tolerance or exemption is applicable is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. If the registration of the pesticide ceases to be suspended and is not canceled under such Act, the Administrator shall rescind any such suspension of a tolerance or exemption.

"(3)(A) At the time the Administrator makes a determination under section 3A(h)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act regarding an ingredient of a pesticide—

"(i) any tolerance established under subsection (b) for residues of a pesticide chemical that is or contains such ingredient or any exemption from the need for such a tolerance established under subsection (c) or a food additive regulation for residues of a pesticide chemical established under section 409 shall be reassessed; and

"(ii) the Administrator shall—

"(I) make a determination whether such tolerance, exemption from tolerance, or regulation meets the requirements of this Act; and

"(II) confirm, establish, amend, or revoke such tolerance, exemption, or regulation in accordance with the requirements of this section.

"(B) Any tolerance, exemption, or regulation that is confirmed, established, or amended under subparagraph (A)(ii)(II) shall not become effective until the Administrator determines that a practical method for detecting residues in or on food or feed is available in order to enforce such tolerance, exemption, or regulation.

"(4) Notwithstanding the foregoing provisions of this subsection, the Administrator, by regulation, may reasonably limit the application of a revocation or suspension of a tolerance or exemption from a tolerance as necessary to prevent the imposition of restrictions on the imports of a particular agricultural commodity from a particular country, except that no such limitation may be effected unless the Administrator determines—

"(A) the tolerance or exemption satisfies the criteria of subsection (b) or (c); and

"(B) there is not available an effective alternative pesticide that may legally be used on the particular agricultural commodity in such country.".

(b) PROCEDURE.—Section 408(m) of such Act is amended by striking out "The" and inserting in lieu thereof "Except as provided in subsection (p), the".

TITLE XXV—CLARIFYING AND TECHNICAL AMENDMENTS

SEC. 2501. CLARIFYING AMENDMENTS.

(a) CERTIFICATION OF PESTICIDE DEALERS.—The last sentence of section 4(a)(1) (7 U.S.C. 136b(a)(1)) is amended by inserting "by regulation" after "may".

(b) REGISTRATION OF ESTABLISHMENTS.—Section 7(c)(1) (7 U.S.C. 136e(c)(1)) is amended—

(1) in the first sentence, by striking out "shall inform the Administrator" and inserting in lieu thereof "shall, in accordance with regulations promulgated by the Administrator, submit to the Administrator a report";

(2) in the first sentence, by striking out "of the" and inserting in lieu thereof "describing"; and

(3) in the second sentence, by striking out "information" and inserting in lieu thereof "report".

(c) AUTHORITY OF ADMINISTRATOR.—Section 25(c) (7 U.S.C. 136w(c)) is amended—

(1) by inserting "or by regulation" after "hearing"; and

(2) in paragraph (5), by striking out "prescribe regulations requiring" and inserting in lieu thereof "require".

SEC. 2502. TECHNICAL AMENDMENTS.

(a) SECTION 2.—Section 2 (7 U.S.C. 136) is amended—

(1) in subsection (c), by striking out "if:" and inserting in lieu thereof "if—";

(2) in subsection (p)(2), by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services";

(3) in subsection (q)(2)(A), by striking out "if:" and inserting in lieu thereof "if—";

(4) in subsection (q)(2)(C)(iii), by striking out ": *Provided*, That" and inserting in lieu thereof ", except that";

(5) in subsection (u)—

(A) by striking out ": *Provided*, That" and inserting in lieu thereof ", except that";

(B) by striking out "(1)(a)";

(C) by striking out "or (b)";

(D) by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services";

(E) by striking out "(2) that" and inserting in lieu thereof "that"; and

(F) by striking out "an article covered by clause (1) of this proviso" and inserting in lieu thereof "a new animal drug"; and

(6) in subsection (ee)—

(A) by striking out ": *Provided,* That the term" and inserting in lieu thereof ", except that the term";

(B) by striking out "or" before clause (4);

(C) by striking out ": *Provided further,* That the term also shall not include" and inserting in lieu thereof ", (5)";

(D) by striking out "or any use" and inserting in lieu thereof "or (6) any use"; and

(E) by striking out ": *And provided further,* That after" and inserting in lieu thereof a period and "After".

(b) SECTION 3.—Section 3 (7 U.S.C. 136a) is amended—

(1) in subsection (c)(1)(D), by striking out "subsection (c)(2)(D) of this section" and inserting in lieu thereof "paragraph (2)(D)";

(2) in subsection (c)(1)(D)(i)—

(A) by striking out ": *Provided,* That such" and inserting in lieu thereof a period and "Such"; and

(B) by striking out the semicolon at the end thereof and inserting in lieu thereof a period;

(3) in subsection (c)(1)(D)(ii)—

(A) by striking out "except as" and inserting in lieu thereof "Except as";

(B) by striking out "subparagraph (D)(i) of this paragraph" and inserting in lieu thereof "clause (i)"; and

(C) by striking out the semicolon at the end thereof and inserting in lieu thereof a period;

(4) in subsection (c)(1)(D)(iv) (as redesignated by section 204(1) of this Act)—

(A) by striking out "after expiration" and inserting in lieu thereof "After expiration";

(B) by striking out "subparagraphs (D)(i) and (D)(ii) of this paragraph" and inserting in lieu thereof "clauses (i), (ii), and (iii)"; and

(C) by striking out the semicolon at the end thereof and inserting in lieu thereof a period;

(5) in subsection (c)(2)—

(A) by striking out "(2)(A) DATA IN SUPPORT OF REGISTRATION.—The" and inserting in lieu thereof the following:

"(2) DATA IN SUPPORT OF REGISTRATION.—

"(A) The";

(B) by indenting all of subparagraph (A) (as amended by the preceding provisions of this Act) two ems, so as to align its left margin with the margin of subparagraph (A) of section 3(d)(1);

(C) in subparagraph (B), by striking out "(B)" and all that follows through "(i) If" and inserting in lieu thereof the following:

"(B)(i) If";

(D) by realigning clauses (iii), (iv), and (v) of subparagraph (B) (as amended by the preceding provisions of this Act) two ems to the left, so as to align the left margin of each clause with the margin of subparagraph (A) (as amended by subparagraph (B) of this paragraph);

(E) in the fourth sentence of subparagraph (B)(iv), by striking out ": *Provided,* That the" and inserting in lieu thereof a period and "The";

(F) in the first sentence of subparagraph (B)(v), by striking out "subsection (c)(1)(D) of this section" and inserting in lieu thereof "paragraph (1)(D)";

(G) in subparagraph (C), by striking out "SIMPLIFIED PROCEDURES.—"; and

(H) by indenting all of subparagraph (C) two ems, so as to align its left margin with the margin of subparagraph (A) (as amended by subparagraph (B) of this paragraph);

(6) in subsection (c)(7), by striking out "subsection (c)(5) of this section" each place it appears and inserting in lieu thereof "paragraph (5)";

(7) in the second sentence of subsection (c)(7)(A), by striking out ": *Provided,* That if" and inserting in lieu thereof a period and "If";

(8) in subsection (d)(1)(A)—

(A) in the first sentence, by striking out ", provided that if" and inserting in lieu thereof a period and "If"; and

(B) in the last sentence, by striking out ": *Provided, however,* That the" and inserting in lieu thereof a period and "The";

(9) in subsection (d)(1)(C)(ii), by striking out the last sentence and inserting in lieu thereof the following new sentence: "Any such regulation shall be reviewable in accordance with section 16(e)."; and

(10) in subsection (f)(2), by striking out ": *Provided,* That as" and inserting in lieu thereof a period and "As".

(c) SECTION 4.—Section 4(a)(1) (7 U.S.C. 136b(a)(1)) is amended—

(1) by striking out ": *Provided,* That such" and inserting in lieu thereof a period and "Such"; and

(2) by striking out ": *Provided, however,* That the" and inserting in lieu thereof a period and "The".

(d) SECTION 5.—The last sentence of section 5(g) (7 U.S.C. 136c(g)) is amended by striking out ": *Provided,* That such" and inserting in lieu thereof a period and "Such".

(e) SECTION 6.—Section 6 (7 U.S.C. 136d) is amended—

(1) in subsection (c), by striking out "Agency" each place it appears and inserting in lieu thereof "Administrator";

(2) in subsection (c)(1), by running into the second sentence the undesignated paragraph in that subsection;

(3) in the second sentence of subsection (c)(3)—

(A) by striking out "(i)" and inserting in lieu thereof "(A)"; and

(B) by striking out "(ii)" and inserting in lieu thereof "(B)"; and

(4) in the second sentence of subsection (e)(2), by striking out ": *Provided,* That the" and inserting in lieu thereof a period and "The".

(f) SECTION 10.—Section 10(d) (7 U.S.C. 136h(d)) is amended—

(1) in paragraph (1)—

(A) by striking out ": *Provided,* That the" and inserting in lieu thereof a period and "The"; and

(B) by striking out ": *Provided further,* That this" and inserting in lieu thereof a period and "This"; and

(2) in the second sentence of paragraph (3), by striking out ": *Provided,* That where" and inserting in lieu thereof a period and "Where".

(g) SECTION 12.—Section 12(a)(2)(F) (7 U.S.C. 136j(a)(2)(F)) is amended by striking out ": *Provided,* That it" and inserting in lieu thereof a period and "It".

(h) SECTION 13.—Section 13 (7 U.S.C. 136k) is amended—

(1) in subsection (b), by moving the last sentence in paragraph (3) after such paragraph as a full measure sentence; and

(2) in the first sentence of subsection (c), by striking out ": *Provided,* That upon" and inserting in lieu thereof a period and "On".

(i) SECTION 15.—Section 15(a) (7 U.S.C. 136m(a)) is amended by striking out "(i)" and "(ii)".

(j) SECTION 16.—Subsection (a) of section 16 (7 U.S.C. 136n) is amended to read as follows:

"(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.".

(k) SECTION 17.—Section 17(c) (7 U.S.C. 136o(c)) is amended—

(1) by striking out ": *Provided,* That the" and inserting in lieu thereof a period and "The"; and

(2) by striking out ": *And provided further,* That all" and inserting in lieu thereof a period and "All".

(l) SECTION 18.—Section 18 (7 U.S.C. 136p) is amended—

(1) in the heading, by inserting "**AND STATE**" after "**FEDERAL**"; and

(2) by running in the second sentence after the first sentence.

(m) SECTION 19.—Section 19(a) (7 U.S.C. 136q(a)) is amended by striking out "canceled under section 6(c)" and inserting in lieu thereof "suspended under section 6(c) and canceled".

(n) SECTION 21.—Section 21 (7 U.S.C. 136s) is amended—

(1) in subsection (a), by inserting "SECRETARY OF AGRICULTURE.—" after the subsection designation;

(2) in subsection (b), by inserting "VIEWS.—" after the subsection designation; and

(3) in subsection (c), by inserting "NOTICE.—" after the subsection designation.

(o) SECTION 24.—Section 24 (7 U.S.C. 136v) is amended—

(1) in subsection (b), by inserting "UNIFORMITY.—" after the subsection designation; and

(2) in subsection (c)—

(A) by striking out "(c)(1) A" and inserting in lieu thereof the following:

"(c) ADDITIONAL USES.—

"(1) A"; and

(B) by indenting each paragraph two ems, so as to align the left margin of each paragraph with the margin of paragraph (2) of section 25(f) (as added by section 2003 of this Act).

(p) SECTION 25.—Section 25 (7 U.S.C. 136w) is amended—

(1) in subsection (a)—

(A) by striking out "(a)(1) REGULATIONS.—The" and inserting in lieu thereof the following:

"(a) IN GENERAL.—

"(1) REGULATIONS.—The";

(B) by indenting all of paragraphs (1) and (3) two ems, so as to align the left margin of each paragraph with the margin of paragraph (2) of section 25(f) (as added by section 2003 of this Act);

(C) in paragraph (2), by striking out "(2) PROCEDURE.—" and inserting in lieu thereof the following:

"(2) PROCEDURE.—";

(D) by indenting each subparagraph of paragraph (2) two ems, so as to align the left margin of each subparagraph with the margin of subparagraph (A) of section 25(f)(1) (as added by section 2003 of this Act);

(E) in paragraph (2)—

(i) in subparagraph (A), by striking out "PROPOSED REGULATIONS.—";

(ii) in subparagraph (B), by striking out "FINAL REGULATIONS.—";

(iii) in subparagraph (C), by striking out "TIME REQUIREMENTS.—"; and

(iv) in subparagraph (D), by striking out "PUBLICATION IN THE FEDERAL REGISTER.—"; and

(F) in paragraph (3), by striking out "Committee on Agriculture and Forestry" and inserting in lieu thereof "Committee on Agriculture, Nutrition, and Forestry"; and

(2) in the second sentence of subsection (e), by striking out ": *Provided*, That whenever" and inserting in lieu thereof a period and "Whenever".

(q) SECTION 26.—Section 26 (7 U.S.C. 136w–1) is amended—

(1) in subsection (a), by inserting "IN GENERAL.—" after the subsection designation;

(2) in subsection (a)(1), by striking out "; *Provided*, That the" and inserting in lieu thereof ", except that the";

(3) in subsection (b), by inserting "SPECIAL RULES.—" after the subsection designation; and

(4) in subsection (c), by inserting "ADMINISTRATOR.—" after the subsection designation.

(r) SECTION 27.—Section 27 (7 U.S.C. 136w–2) is amended—

(1) in subsection (a), by inserting "REFERRAL.—" after the subsection designation;

(2) in subsection (b), by inserting "NOTICE.—" after the subsection designation; and

(3) in subsection (c), by inserting "CONSTRUCTION.—" after the subsection designation.

(s) REDESIGNATION OF SECTIONS 3A AND 4.—

(1) REDESIGNATION OF SECTION 4 AS SECTION 11.

(A) IN GENERAL.—Section 4 (7 U.S.C. 136b) (as amended by the preceding provisions of this Act) is redesignated as section 11 (as amended by section 1001).

(B) CONFORMING AMENDMENTS.—Sections 2(e)(3) (as amended by section 101 of this Act), 5(f), 19(e)(2) (as added by section 1601 of this Act), 23(a)(1)(C) (as amended by section 1801 of this Act), and 26(b) are each amended by striking out "section 4" and inserting in lieu thereof "section 11".

(2) Redesignation of section 3A as section 4.

(A) In general.—Section 3A (as added by section 301 of this Act) is redesignated as section 4.

(B) Conforming amendments.—

(i) FIFRA.—Sections 6(g)(2) (as added by section 506 of this Act), 12(a)(2)(J) (as amended by section 1101(a)(2)(C) of this Act), and 24(a)(2)(A)(ii) (as amended by section 1901 of this Act) are each amended by striking out "3A" and inserting in lieu thereof "4".

(ii) Federal Food, Drug, and Cosmetic Act.—Section 408(p)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(p)(3)(A)) (as added by section 2403(a) of this Act) is further amended by striking out "3A" and inserting in lieu thereof "4".

SEC. 2503. TABLE OF CONTENTS AMENDMENTS.

Subsection (b) of section 1 (7 U.S.C. prec. 121) is amended to read as follows:

"(b) Table of Contents.—

"Section 1. Short title and table of contents.
  "(a) Short title.
  "(b) Table of contents.

"Sec. 2. Definitions.
  - "(a) Active ingredient.
  - "(b) Administrator.
  - "(c) Adulterated.
  - "(d) Animal.
  - "(e) Applicator.
    - "(1) Commercial applicator.
    - "(2) Private applicator.
    - "(3) Certified applicator.
    - "(4) Under the direct supervision of a certified applicator.
  - "(f) Defoliant.
  - "(g) Desiccant.
  - "(h) Device.
  - "(i) District court.
  - "(j) Environment.
  - "(k) Fungus.
  - "(l) Imminent hazard.
  - "(m) Inert ingredient.
  - "(n) Ingredient statement.
  - "(o) Insect.
  - "(p) Label and labeling.
    - "(1) Label.
    - "(2) Labeling.
  - "(q) Misbranded.
  - "(r) Nematode.
  - "(s) Person.
  - "(t) Pest.
  - "(u) Pesticide.
  - "(v) Plant regulator.
  - "(w) Producer and produce.
  - "(x) Protect health and the environment.
  - "(y) Registrant.
  - "(z) Registration.
  - "(aa) State.
  - "(bb) Unreasonable adverse effects on the environment.
  - "(cc) Weed.
  - "(dd) Establishment.
  - "(ee) To use any registered pesticide in a manner inconsistent with its labeling.
  - "(ff) Antimicrobial.
  - "(gg) Container.
  - "(hh) Outstanding data requirement.
    - "(1) In general.
    - "(2) Factors.
  - "(ii) Pesticide dealer.
    - "(1) In general.
    - "(2) Exception.
  - "(jj) Pesticide testing facility.
  - "(kk) To distribute or sell.

"Sec. 3. Registration of pesticides.
  - "(a) Requirement of registration.
  - "(b) Exemptions.
  - "(c) Procedure for registration.

- "(1) Statement required.
- "(2) Data in support of registration.
- "(3) Time for acting with respect to application.
- "(4) Notice of application.
- "(5) Approval of registration.
- "(6) Denial of registration.
- "(7) Registration under special circumstances.
- "(8) Public interim administrative review.
- "(9) Preregistration access to data.

"(d) Classification of pesticides.
- "(1) Classification for general use, restricted use, or both.
- "(2) Change in classification.
- "(3) Change in classification from restricted use to general use.

"(e) Products with same formulation and claims.

"(f) Miscellaneous.
- "(1) Effect of change of labeling or formulation.
- "(2) Registration not a defense.
- "(3) Authority to consult other Federal agencies.

"(g) Priority list and data requirements for inert ingredients.
- "(1) Establishment of list.
- "(2) Publication of list.
- "(3) Judicial review.
- "(4) Number of ingredients.
- "(5) Additional data.
- "(6) Evaluation.
- "(7) Construction.

"(h) Antimicrobial standards.
- "(1) Standards.
- "(2) Definition.

"(i) Neurotoxicological and behavioral effects testing.

"Sec. 4. Reregistration of registered pesticides.

"(a) General rule.
- "(1) Pesticides.
- "(2) Basis.

"(b) Special authorities of Administrator.
- "(1) Guidelines.
- "(2) Monitoring.
- "(3) Suspensions and penalties.

"(c) Reregistration phases.

"(d) Phase one.
- "(1) Priority for reregistration.
- "(2) Reregistration lists.
- "(3) Judicial review.
- "(4) Notice to registrants.

"(e) Phase two.
- "(1) In general.
- "(2) Notice of intent to seek or not to seek reregistration.
- "(3) Missing or inadequate data.
- "(4) Time periods.
- "(5) Cancellation and removal.

"(f) Phase three.
- "(1) Information about studies.
- "(2) Time periods.
- "(3) Cancellation.

"(g) Phase four.
    "(1) Independent review and identification of outstanding data requirements.
    "(2) Time periods.
"(h) Phase five.
    "(1) Data review.
    "(2) Reregistration and other actions.
"(i) Compensation of data submitter.
"(j) Fees.
    "(1) Annual reregistration fees.
    "(2) Payment date.
    "(3) Other fees.
    "(4) Apportionment.
"(k) Exemption of certain registrants.
"(l) Reregistration fund.
    "(1) Establishment.
    "(2) Source and use.
    "(3) Unused funds.
    "(4) Accounting.
"(m) Judicial review.
"Sec. 5. Experimental use permits.
"(a) Issuance.
"(b) Temporary tolerance level.
"(c) Use under permit.
"(d) Studies.
"(e) Revocation.
"(f) State issuance of permits.
"(g) Exemption for agricultural research agencies.
"Sec. 6. Administrative review; suspension.
"(a) Cancellation after five years.
"(b) Cancellation and change in classification or labels.
    "(1) Notice of cancellation or change in classification.
    "(2) Hearing.
    "(3) Factors.
    "(4) Label changes.
"(c) Suspension.
    "(1) Order.
    "(2) Expedite hearing.
    "(3) Emergency order.
    "(4) Judicial review.
"(d) Public hearings.
"(e) Conditional registration.
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    "(3) Procedures.
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"(2) Copies.
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"(1) In general.
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"(2) Notice not required.
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"(e) Disclosure to contractors.
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    - "(2) Certified commercial applicators.
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    - "(2) Certified private applicators.
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  - "(f) Recertification and reregistration.
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    - "(2) Training material.
    - "(3) Recertification.
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  - "(h) Minimum standards for trainers and training programs.
    - "(1) Training of commercial applicators.
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  - "(a) Stop sale, etc., orders.
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"(2) Private applicator.
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"(1) Report.
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"(b) Review by Court of Appeals.
"(c) Jurisdiction of district courts.
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"(c) Provisions for unused quantities.
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"(2) Report.
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TITLE XXVI—EFFECTIVE DATE

SEC. 2601. EFFECTIVE DATE.

Except as otherwise provided in this Act, the amendments made by this Act shall take effect on the expiration of 60 days after the date of enactment of this Act.

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